

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION )  
and GENEVANT SCIENCES GmbH, ) **REDACTED**  
)  
Plaintiffs, )  
)  
v. ) C.A. No. 22-252-MSG  
)  
MODERNA, INC. and MODERNATX, INC., )  
)  
Defendants. )

**LETTER TO THE HONORABLE MITCHELL S. GOLDBERG  
FROM NATHAN R. HOESCHEN**

OF COUNSEL:  
David I. Berl  
Adam D. Harber  
Thomas S. Fletcher  
Jessica Palmer Ryen  
Shaun P. Mahaffy  
Jihad J. Komis  
Anthony H. Sheh  
Matthew W. Lachman  
Philip N. Haunschild  
Falicia Elenberg  
WILLIAMS & CONNOLLY LLP  
680 Maine Avenue S.W.  
Washington, DC 20024  
(202) 434-5000  
*Attorneys for Plaintiff Genevant  
Sciences GmbH*

Daralyn J. Durie  
Adam R. Brausa  
Eric C. Wiener  
Annie A. Lee  
Shaelyn K. Dawson  
MORRISON & FOERSTER LLP  
425 Market Street  
San Francisco, CA 94105-2482  
(415) 268-6080

John W. Shaw (No. 3362)  
Karen E. Keller (No. 4489)  
Nathan R. Hoeschen (No. 6232)  
Emily S. DiBenedetto (No. 6779)  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 298-0700  
jshaw@shawkeller.com  
kkeller@shawkeller.com  
nhoeschen@shawkeller.com  
edibenedetto@shawkeller.com  
*Attorneys for Plaintiffs*

Kira A. Davis  
MORRISON & FOERSTER LLP  
707 Wilshire Boulevard  
Los Angeles, CA 90017-3543  
(213) 892-5200

David N. Tan  
MORRISON & FOERSTER LLP  
2100 L Street, NW, Suite 900  
Washington, DC 20037  
(202) 887-1500  
*Attorneys for Plaintiff Arbutus  
Biopharma Corporation*

Dated: December 15, 2023

# SHAW KELLER LLP

Nathan R. Hoeschen  
I.M. Pei Building  
1105 North Market Street, 12<sup>th</sup> Floor  
Wilmington, DE 19801  
(302) 298-0709 – Direct  
nhoeschen@shawkeller.com

## **BY CM/ECF**

The Honorable Mitchell S. Goldberg  
U.S. District Court for the Eastern District of Pennsylvania  
James A. Byrne U.S. Courthouse, Room 17614  
601 Market Street, Philadelphia, PA 19106-1797

**FILED UNDER SEAL**

**HIGHLY CONFIDENTIAL  
OUTSIDE COUNSEL'S EYES ONLY**

Re: *Arbutus Biopharma Corporation, et. al. v. Moderna, Inc., et. al.* C.A. No. 22-252-MSG

Dear Judge Goldberg:

Plaintiffs move to compel Defendant Moderna to produce the most basic discovery one can request in a patent case: samples of the accused product. Moderna has agreed to produce samples from only a minority of the accused product batches—about 480 expired batches plus a handful of other batches out of approximately 2000 (if not more) at issue.<sup>1</sup> But Moderna refuses to produce samples of other batches, [REDACTED], all while maintaining the right to contest infringement of those unproduced batches. This position is untenable. Moderna's accused product varies batch-by-batch. Plaintiffs thus seek samples from the remaining batches (or a sufficient sampling, if the prejudice of Moderna's withholding of relevant discovery is mitigated by precluding it from disputing infringement of withheld batches). Plaintiffs also move to compel [REDACTED], along with associated data.

**Drug Product Samples (RFP No. 97).** A central issue in this case is whether LNPs in batches of Moderna's vaccine embody the lipid ratios covered by Plaintiffs' patents.<sup>2</sup> Each batch contains trillions of LNPs, each of which can have a different lipid ratio. Unlike cases involving products like an iPhone, where each product of the same model is essentially identical, discovery to date has revealed batch-to-batch variation in the lipid ratios of Moderna's vaccine. Moderna's own documents show that [REDACTED], which affects the infringement inquiry. *See, e.g.*, Ex. 1 (showing [REDACTED]); Ex. 2 at \*146, \*184 (showing [REDACTED]). And that [REDACTED]

Moderna has no reasonable basis to dispute the salience of samples from each batch of its vaccine, and any contrary argument contravenes the case law.<sup>3</sup> The only case Moderna has cited

<sup>1</sup> The parties also dispute discovery concerning batches manufactured overseas, which Plaintiffs allege were sold or offered for sale (and thereby infringed) in the U.S. Plaintiffs are filing a separate motion on this dispute, but for clarity, seek samples from all Moderna's batches, including those manufactured overseas. Moderna to date has only identified U.S.-manufactured batches.

<sup>2</sup> While Moderna contends that the "particle[s]" in Plaintiffs' claims must be "finished" in the narrow sense of not being subject to further processing, this and other claim construction disputes, D.I. 129, do not affect this dispute on the particles in undisputedly *finished* drug product samples.

<sup>3</sup> *Everlight Elecs. Co. v. Nichia Corp.*, 2013 WL 6713789 at \*2 (E.D. Mich. Dec. 20, 2013) (compelling production of "more than 1,000 Accused LED Products"); *Invensas Corp. v. Renesas*

on this issue involves a simple product (“test cups” for urine screening) without batch-to-batch variation. *Rembrandt Diagnostics, LP v. Innovocon, Inc.*, 2017 WL 4391707 (S.D. Cal. Oct. 3, 2017). Given Moderna’s own data reflecting variation between batches, it is beyond cavil that samples of *each batch* matter in this case. Indeed, despite repeatedly refusing and delaying even to identify infringing batches and then offering only a handful, Ex. 3 at 1, Moderna abruptly reversed course and made an exploding offer of approximately 480 expired batches, which Plaintiffs accepted. Ex. 4 at 4, 7–9. As to the remaining batches, however, Moderna has agreed only to produce a single batch from each version or “part number” of its vaccine—roughly a dozen batches. Moderna’s proposal is prejudicial, and the justifications it has offered, related to its own testing and burden, are dubious and do not justify depriving Plaintiffs of this critical discovery.

Moderna’s proposal to produce a sample from a single batch per part number—when part numbers can comprise *hundreds* of batches—prejudices Plaintiffs substantially, and ignores the undisputed variability in lipid ratios across batches. This prejudice is acute because *Moderna* intends to select unilaterally the single batch. *See* Ex. 5 at 1. Nor does Moderna’s proposal permit Plaintiffs to test both expired and unexpired batches, which is critical because Moderna (despite producing only expired batches) intends to dispute test results on the basis of expiry.

The fundamental problem with Moderna’s proposal is that Moderna maintains its right to argue that *unproduced* batches do not infringe. Moderna cannot decline to produce batches only later to dispute infringement of what it withheld, thereby “den[ying Plaintiffs] the opportunity to conduct discovery.” *Prism Techs., LLC v. T-Mobile USA Inc.*, 2015 WL 5883764, at \*3 (D. Neb. Oct. 8, 2015). While Plaintiffs are amenable to Moderna limiting its sample production (albeit to more than one sample per part number, not unilaterally selected by Moderna), any such agreement “would have to include a stipulation [by Moderna] to not raise future objections” with respect to batches that have been withheld. *Wonderland Nurserygoods Co. v. Baby Trend, Inc.*, 2021 WL 2315191, at \*4 (C.D. Cal. June 7, 2021); *Apple Inc. v. Samsung Elecs. Co.*, 2012 WL 1511901, at \*6 (N.D. Cal. Jan. 27, 2012) (“[T]o reduce Samsung’s burden . . . Samsung can negotiate a stipulation that its production adequately represents . . . the entire set of accused products.”). While Plaintiffs bear the burden of proving infringement, the choice for Moderna is simple: produce samples from each batch or agree not to dispute infringement of unproduced batches.

Moderna has argued that Plaintiffs do not need samples of every batch because Moderna has conducted its own testing. But it is a basic principle of discovery that Plaintiffs need not accept Moderna’s testing as a substitute for their own. *Vitamins Online, Inc. v. Heartwise, Inc.*, 2016 WL 1305144, at \*1–2 (D. Utah Mar. 31, 2016) (compelling production of lots despite defendant’s claim that it “already . . . tested” “a majority of those lots”); *Seer Sys., Inc. v. Beatnik, Inc.*, 2006 WL 1180058 at \*1–2 (N.D. Cal. May 3, 2006) (ordering samples *in addition* to technical documents). Moderna may tout its production of “400,000 pages” of regulatory submissions, but those documents largely comprise information irrelevant to infringement and are no substitute for the highly relevant samples of the accused product itself. Indeed, in all of the cases cited above,

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*Elecs. Corp.*, 2013 WL 1776112, at \*1 (D. Del. Apr. 24, 2013); *P&G Co. v. Be Well Mktg., Inc.*, 2013 WL 152801, at \*5–6 (M.D. Pa. Jan. 15, 2013); *Integra LifeSciences Corp. v. HyperBranch Med. Tech., Inc.*, 2016 WL 675553, at \*1 (D. Del. Feb. 12, 2016); *3Com Corp. v. D-Link Sys., Inc.*, 2007 WL 949596, at \*1–2 (N.D. Cal. Mar. 27, 2007) (ordering production of code for “all” accused products and “all missing versions”); *Alloc, Inc. v. Unilin Beheer B.V.*, 2006 WL 757871, at \*4 (E.D. Wis. Mar. 24, 2006) (rejecting production only of products made after a certain date).

substantial document discovery did not obviate the need for sufficient samples. In any event, Moderna's own testing need not be accepted uncritically—particularly given that Moderna conducted it while attacking the asserted patents unsuccessfully before the PTAB and Federal Circuit—and where the testing [REDACTED].

E.g., D.I. 1-1, 91. While the former might be relevant to the latter, they are not the same.

Moderna also has argued that the production of samples is burdensome. Any burden is proportional to the hundreds of millions of infringing doses it has sold (each batch contains tens of thousands of doses). There is no dispute that samples from each batch are readily available and accessible as part of Moderna's FDA "regulatory retain." Ex. 6 at 3; *Vitamins Online*, 2016 WL 1305144, at \*2 (compelling samples from retain). This "regulatory retain" necessarily permits Moderna to furnish, expeditiously, any batch(es) FDA requests. It is not burdensome for Moderna to produce samples of its batches; it simply does not want to produce them *to Plaintiffs*. Indeed, contrary to any notion of burden here, Moderna shifted, on a dime, from arguing for months that producing more than 13 batches was "extremely burdensome" to demanding that Plaintiffs accept 480 batches within 3 business days. Ex. 4 at 1. Moderna is able to produce samples when it so chooses. Regardless, Moderna's purported burden cannot outweigh the prejudice from its single-batch-per-part-number proposal. While Plaintiffs have sought, for months, a compromise that limits Moderna's burden without prejudicing Plaintiffs, any compromise in which Moderna produces samples from fewer than all batches is undermined by Moderna's unqualified reservation to dispute infringement as to unproduced batches. Moderna cannot simultaneously deny Plaintiffs discovery while reserving its ability to dispute infringement of what it has withheld.

[REDACTED] **and Raw Data (RFP Nos. 108, 174).** In its process for making the accused vaccine, Moderna [REDACTED] Ex. 7 at \*837. Moderna objects that [REDACTED] and therefore does not infringe. Plaintiffs therefore requested samples of the particles in Moderna's process [REDACTED], but Moderna responded that these particles are impossible to collect. The ratio in this unavailable intermediate particle differs from the final drug product and can separately infringe the asserted claims to "particle[s]." Ex. 8 at \*169–70. As such, Plaintiffs requested samples of [REDACTED], from which infringement of the unavailable intermediate can be determined. Ex. 5 at 3. Moderna refused to produce samples, as well as raw data from its lipid testing of [REDACTED].

The requested samples and data are relevant to infringement. [REDACTED], but Moderna uses [REDACTED]. The lipid ratios of [REDACTED]—which Plaintiffs seek to ascertain by testing samples and obtaining Moderna's data—are relevant to the lipid composition of potentially infringing particles [REDACTED]. Moreover, Moderna's documents reflect that [REDACTED].

[REDACTED] Ex. 8 at \*167. Moderna's use of [REDACTED] in its "manufacturing processes [thus] bear[s] upon the properties of its finished products," entitling Plaintiffs to discovery. *Medtronic Ave, Inc. v. Adv. Cardio. Sys.*, 2004 WL 115594, at \*3 (D. Del. Jan. 13, 2004). Sample production can be conducted according to the principles above; and the raw data underlying Moderna's testing in light of its stated intent to rely on its own test results is plainly relevant.

SHAW KELLER LLP

Page 4

Respectfully submitted,

*/s/ Nathan R. Hoeschen*

Nathan R. Hoeschen (No. 6232)

cc: Clerk of the Court (by CM/ECF)  
All counsel of record (by CM/ECF & Email)

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION	)	
and GENEVANT SCIENCES GmbH,	)	
	)	
Plaintiffs,	)	
	)	C.A. No. 22-252-MSG
v.	)	
	)	
MODERNA, INC. and MODERNATX, INC.,	)	
	)	
Defendants.	)	

**RULE 7.1.1 STATEMENT**

Pursuant D. Del. LR 7.1.1, the undersigned counsel hereby certifies that a reasonable effort was made to reach agreement on the subject of this motion.

OF COUNSEL:  
David I. Berl  
Adam D. Harber  
Thomas S. Fletcher  
Jessica Palmer Ryen  
Shaun P. Mahaffy  
Jihad J. Komis  
Anthony H. Sheh  
Matthew W. Lachman  
Philip N. Haunschild  
Falicia Elenberg  
WILLIAMS & CONNOLLY LLP  
680 Maine Avenue S.W.  
Washington, DC 20024  
(202) 434-5000  
*Attorneys for Plaintiff Genevant  
Sciences GmbH*

/s/ Nathan R. Hoeschen  
John W. Shaw (No. 3362)  
Karen E. Keller (No. 4489)  
Nathan R. Hoeschen (No. 6232)  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 298-0700  
jshaw@shawkeller.com  
kkeller@shawkeller.com  
nhoeschen@shawkeller.com  
*Attorneys for Plaintiffs*

Daralyn J. Durie  
Adam R. Brausa  
Eric C. Wiener  
Annie A. Lee  
Shaelyn K. Dawson  
MORRISON & FOERSTER LLP  
425 Market Street  
San Francisco, CA 94105-2482  
(415) 268-6080

Kira A. Davis  
MORRISON & FOERSTER LLP  
707 Wilshire Boulevard  
Los Angeles, CA 90017-3543  
(213) 892-5200

David N. Tan  
MORRISON & FOERSTER LLP  
2100 L Street, NW, Suite 900  
Washington, DC 20037  
(202) 887-1500  
*Attorneys for Plaintiff Arbutus  
Biopharma Corporation*

Dated: December 15, 2023



# **Exhibit 1**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ARBUTUS BIOPHARMA CORPORATION  
and GENEVANT SCIENCES GMBH

*Plaintiffs,*

v.

MODERNA, INC. and MODERNATX,  
INC.,

*Defendants.*

C.A. No. 22-252-MSG

**CONTAINS INFORMATION  
MODERNA DESIGNATED HIGHLY  
CONFIDENTIAL – OUTSIDE  
COUNSEL EYES ONLY**

**PLAINTIFFS’ INITIAL INFRINGEMENT CONTENTIONS**

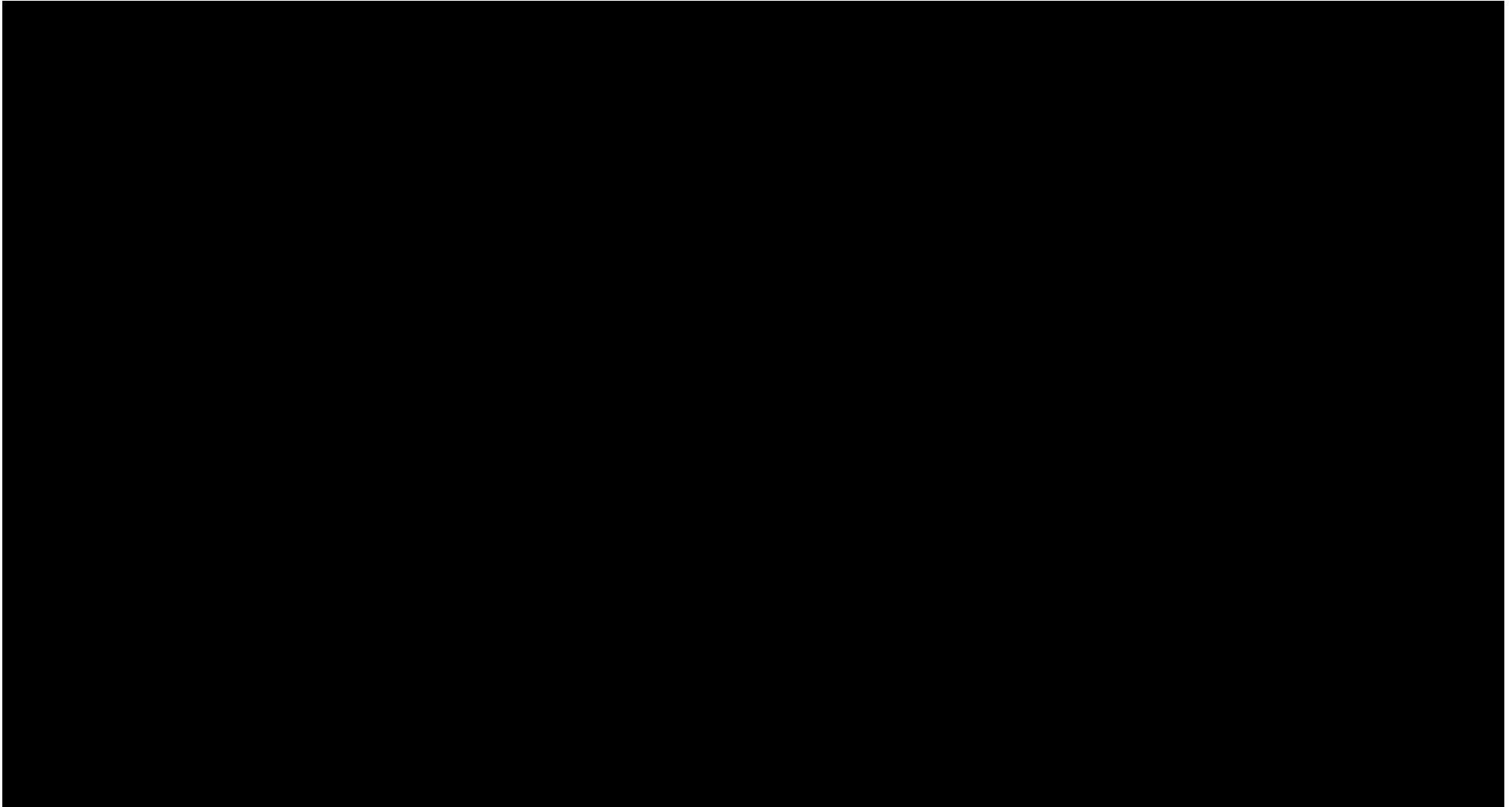
Pursuant to the Court’s Scheduling Order (D.I. 72) and Paragraph 4(c) of the Court’s Default Standard for Discovery, Including Discovery of Electronically Stored Information, Plaintiffs Arbutus Biopharma Corporation (“Arbutus”) and Genevant Sciences GmbH (“Genevant”) disclose their initial infringement contentions regarding U.S. Patent Nos. 8,058,069 (“the ’069 patent”); 8,492,359 (“the ’359 patent”); 8,822,668 (“the ’668 patent”); 9,364,435 (“the ’435 patent”); 9,504,651 (“the ’651 patent”); and 11,141,378 (“the ’378 patent”) to Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, “Moderna”).

Plaintiffs’ initial infringement contentions are based on the information currently available to, and known by, Plaintiffs. Fact discovery is ongoing, and Plaintiffs have not yet obtained any deposition testimony from Moderna. The Court has not yet construed any of the asserted claims of the patents-in-suit. The Court has set a schedule pursuant to which the parties will identify terms for construction, provide proposed constructions, cite evidence supportive of those constructions, confer to narrow the disputes before the Court, and then submit, through briefing and oral presentations, their arguments to the Court. The Court will then construe the disputed

*Arbutus Biopharma Corp. and Genevant Sciences GmbH v. Moderna, Inc., et al.*, C.A. No. 22-252-MSG (D. Del.)

## Paragraph 4(c) Charts – Appendix A

Moderna Lot <sup>2</sup>	Bates Begin	Mfg. Stage	Mfg. Date	% RNA Encapsulation	Total RNA (mg/mL)	Particle Size (nm)	PDI			DSPC (mg/mL)	Cholesterol (mg/mL)	PEG2000-DMG (mg/mL)
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<sup>2</sup> The batches and/or lots listed in Appendix A are based on information currently available and known to Plaintiffs. The data listed in Appendix A report the data as measured and reported by Moderna and/or Moderna's contracted third-party, which Plaintiffs are investigating and reserve the right to amend and/or supplement. Plaintiffs further reserve the right to supplement or amend this listing as additional information is produced by Moderna and/or becomes known to Plaintiffs.

*Arbutus Biopharma Corp. and Genevant Sciences GmbH v. Moderna, Inc., et al.*, C.A. No. 22-252-MSG (D. Del.)

Paragraph 4(c) Charts – Appendix A

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*Arbutus Biopharma Corp. and Genevant Sciences GmbH v. Moderna, Inc., et al.*, C.A. No. 22-252-MSG (D. Del.)

Paragraph 4(c) Charts – Appendix A

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Paragraph 4(c) Charts – Appendix A

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CONTAINS INFORMATION MODERNA DESIGNATED  
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Appendix A  
Page 4 of 6

*Arbutus Biopharma Corp. and Genevant Sciences GmbH v. Moderna, Inc., et al.*, C.A. No. 22-252-MSG (D. Del.)

Paragraph 4(c) Charts – Appendix A

Moderna Lot <sup>2</sup>	Bates Begin	Mfg. Stage	Mfg. Date	% RNA Encapsulation	Total RNA (mg/mL)	Particle Size (nm)	PDI			DSPC (mg/mL)	Cholesterol (mg/mL)	PEG2000-DMG (mg/mL)
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*Arbutus Biopharma Corp. and Genevant Sciences GmbH v. Moderna, Inc., et al.*, C.A. No. 22-252-MSG (D. Del.)

Paragraph 4(c) Charts – Appendix A

Moderna Lot <sup>2</sup>	Bates Begin	Mfg. Stage	Mfg. Date	% RNA Encapsulation	Total RNA (mg/mL)	Particle Size (nm)	PDI			DSPC (mg/mL)	Cholesterol (mg/mL)	PEG2000-DMG (mg/mL)
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**CERTIFICATE OF SERVICE**

I, Karen E. Keller, hereby certify that on April 24, 2023, this document was served on the persons listed below in the manner indicated:

**BY EMAIL:**

Jack B. Blumenfeld  
Brian P. Egan  
MORRIS, NICHOLS, ARSHT & TUNNELL LLP  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@morrisnichols.com  
began@morrisnichols.com

James F. Hurst  
KIRKLAND & ELLIS LLP  
300 North LaSalle  
Chicago, IL 60654  
(312) 862-2000  
james.hurst@kirkland.com

Alina Afinogenova  
KIRKLAND & ELLIS LLP  
200 Clarendon Street  
Boston, MA 02116  
(617) 385-7500  
alina.afinogenova@kirkland.com

Patricia A. Carson, Ph.D.  
Jeanna M. Wacker  
Mark C. McLennan  
Nancy Kaye Horstman  
KIRKLAND & ELLIS LLP  
601 Lexington Avenue  
New York, NY 10022  
(212) 446-4800  
patricia.carson@kirkland.com  
jeanna.wacker@kirkland.com  
mark.mclennan@kirkland.com  
kaye.horstman@kirkland.com

Yan-Xin Li  
KIRKLAND & ELLIS LLP  
555 California Street, 27th Floor  
San Francisco, CA 94104  
(415) 439-1400  
yanxin.li@kirkland.com

/s/ Karen E. Keller

John W. Shaw (No. 3362)  
Karen E. Keller (No. 4489)  
Nathan R. Hoeschen (No. 6232)  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
(302) 298-0700  
jshaw@shawkeller.com  
kkeller@shawkeller.com  
nhoeschen@shawkeller.com  
*Attorneys for Plaintiffs*

# **Exhibit 2**

# **Filed Under Seal**

# **Exhibit 3**

LAW OFFICES  
**WILLIAMS & CONNOLLY**<sub>LLP</sub>\*

ANTHONY H. SHEH  
(202) 434-5436  
asheh@wc.com

680 MAINE AVENUE SW  
WASHINGTON, DC 20024  
(202) 434-5000  
WWW.WC.COM

EDWARD BENNETT WILLIAMS (1920-1988)  
PAUL R. CONNOLLY (1922-1978)

June 29, 2023

**CONTAINS INFORMATION MODERNA DESIGNATED  
HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY**

**Via E-Mail**

Mark C. McLennan  
KIRKLAND & ELLIS LLP  
601 Lexington Avenue  
New York, NY 10022  
(212) 909-3451  
mark.mclennan@kirkland.com

Re: *Arbutus Biopharma Corporation and Genevant Sciences GmbH v. Moderna, Inc.  
and ModernaTX, Inc.*, Case 1:22-cv-00252-MSG (D. Del.)

Dear Mark:

I write to follow-up regarding the parties’ latest meet-and-confer on June 23, 2023, regarding Moderna’s failure to identify batches of the Accused Product. As we have raised repeatedly on our multiple meet-and-confers in March and April, as well as our correspondence dated April 18, April 28, May 11, and June 14, 2023, Moderna’s failure to identify these batches has prejudiced (and continues to prejudice) Plaintiffs’ ability to litigate this case, including by preventing the parties from productively negotiating the scope of sample production. Moderna originally contended that Plaintiffs’ request (in RFP 97) for 50 vials per batch would lead to millions of samples being produced. Since then, Moderna has suggested that the number is not so high, but has provided no information to either substantiate its claims or to provide a starting point for the parties’ negotiations. Despite the passage of more than *four months* since the parties first discussed this issue, Moderna still has not provided the requested information, and its June 12, 2023, supplemental response to Plaintiffs’ Interrogatories Nos. 6 and 11 did not even identify a date certain by which Moderna would do so. Relatedly, Moderna still has not provided the availability of samples from those batches or even confirmed their existence.

To be clear: Plaintiffs seek basic accounting information on Moderna’s batches of Accused Product so that the parties can productively negotiate the scope of sample production. As stated in Plaintiffs’ April 28, 2023 letter, Moderna clearly can—indeed, is required to—provide

WILLIAMS & CONNOLLY LLP

June 29, 2023

Page 2

information regarding its batches and their disposition to the FDA; and so it clearly can also do so in this litigation. *See, e.g.*, MRNA-GEN-00044097 at \*44103. And any information about samples from these batches would, given the storage conditions attendant to them, necessarily be in inventory records that Moderna presumably keeps in the ordinary course of business. To date, Moderna has not articulated the burden of providing this information, and its continued delay is prejudicial to Plaintiffs' ability to conduct discovery in a timely fashion. *See e.g.* June 26, 2019 Transcript from *Merck Sharp & Dohme Corp. v. Alvogen Pine Brook LLC et al.*, C.A. No. 19-310-RGA (Judge Andrews: "[I]t's incumbent on the defendants to make a reasonable effort to get [plaintiffs] unexpired samples, if such things exist, *in a timely fashion.*") (emphasis added) (attached as **Exhibit A**).

On our June 23, 2023 meet-and-confer, the only burden Moderna alluded to was that of completely responding to the other relevant information sought by Plaintiffs' Interrogatories Nos. 6 and 11, such as dispositional and financial/sales information regarding batches of the Accused Product. We understand that Moderna intends to supplement its interrogatory responses to provide this information sometime in July. But Moderna has not articulated any basis for not promptly providing the basic accounting information sufficient to identify batches of Accused Product Moderna months ago agreed was a necessary predicate for further discussions regarding sample production, and Moderna months ago agreed to provide.

Please therefore identify by Friday, July 7, 2023, the batches of the Accused Product that Moderna has manufactured and/or sold, and provide the availability of samples from those batches. If Moderna is not able to do so, please provide a date certain by which Moderna will provide this information. Given the prejudice of Moderna's delay in providing this information to date, Plaintiffs reserve all rights to further relief.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony Sheh", with a stylized, cursive script.

Anthony H. Sheh

# **Exhibit 4**

**From:** [Elenberg, Falicia](#)  
**To:** ["Afinogenova, Alina"](#); [Sheh, Anthony](#); [Haunschild, Philip](#); [McLennan, Mark C.](#)  
**CC:** [#KEModernaSpikevaxService](#); [Li, Yan-Xin](#); [Horstman, N. Kaye](#); ["Arbutus\\_MoFo"](#); [Parrado, Alvaro](#); [Komis, Jihad](#); [Genevant Team](#); [Berl, David](#); [Mahaffy, Shaun](#); [Harber, Adam](#); [Fletcher, Thomas](#); [Ryen, Jessica](#); ["NTan@mofo.com"](#); [Bolte, Erik](#); [\\*jshaw@shawkeller.com](#); ["kkeller@shawkeller.com"](#); ["nhoeschen@shawkeller.com"](#); ["EWiener@mofo.com"](#); ["began@mnat.com"](#); ["tmurray@morrisnichols.com"](#); ["jblumenfeld@morrisnichols.com"](#); [Hurst, James F.](#); [Carson, Patricia A.](#); [Wacker, Jeanna](#)  
**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information) - HIGHLY CONFIDENTIAL OCEO  
**Date:** Monday, December 11, 2023 4:22:00 PM

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Alina,

Thank you for your response.

We are surprised by Moderna's recent and abrupt change in position regarding samples. Up until your November 10th email, Moderna maintained its position that it would produce samples from less than ~1% of batches of the Accused Products manufactured / imported into the U.S. (13 out of over 1000 batches). Moderna refused to engage with Plaintiffs' good faith efforts to negotiate regarding the scope of sample production, an effort that we undertook in based on Moderna's representation about the immense burden associated with sample production. Then, out of the blue, Moderna offered samples from approximately 480 batches. Plaintiffs do not understand how the burden of production could have shifted so suddenly and significantly as to allow Moderna to produce samples from hundreds of batches after claiming for months on end that producing samples from anything more than 13 would be "extremely burdensome" (without producing any evidence of this burden). See September 19, 2023 Letter from M. McLennan at 2. Plaintiffs continue to maintain that Moderna should produce samples from each batch of the Accused Product, especially in light of Plaintiffs' new understanding regarding the true burden of sample production. Plaintiffs request that whatever preparatory efforts Moderna is currently undertaking to produce the offered samples, Moderna also apply to samples from the remaining batches of the Accused Product to prevent further prejudice to Plaintiffs.

We also have questions regarding the timing of sample production. In its November 10th email, Moderna requested that Plaintiffs accept its offer within **3 business days** and stated its understanding that production could be made within two weeks. On the November 17th meet-and-confer, Moderna again conveyed time-pressure to Plaintiffs indicating that the timeline is dictated by the movement of the ~480 samples out of their current facility, which Moderna anticipated would take place within two weeks of the initial offer. Not only did Moderna fail to deliver the samples within the timeframe provided, Moderna failed to respond to Plaintiffs' correspondences for over two weeks. Moderna now claims that it should be in a position to make the production sometime in the month of January (i.e., 1-2 months later than originally indicated), without any explanation for the delay or specificity regarding dates. Plaintiffs are extremely prejudiced by Moderna's continued delay in producing samples **more than one year** after Plaintiffs' requested them. Moderna is putting Plaintiffs in a position to be unable to meet the case schedule, perhaps strategically so, and this is plainly improper. By December 18, 2023, please provide Plaintiffs with a specific explanation of the reasons for the continued delay of sample production.

Thank you,  
 Falicia

**Falicia Elenberg**

**Associate | Williams & Connolly LLP**

680 Maine Avenue, S.W., Washington, DC 20024

202-434-5989 | [felenberg@wc.com](mailto:felenberg@wc.com) | [www.wc.com](http://www.wc.com)

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**From:** Afinogenova, Alina <alina.afinogenova@kirkland.com>

**Sent:** Tuesday, December 5, 2023 9:48 PM

**To:** Sheh, Anthony <ASheh@wc.com>; Haunschild, Philip <phaunschild@wc.com>; McLennan, Mark C. <mark.mclennan@kirkland.com>

**Cc:** #KEModernaSpikevaxService <KEModernaSpikevaxService@kirkland.com>; Li, Yan-Xin <yanxin.li@kirkland.com>; Horstman, N. Kaye <kaye.horstman@kirkland.com>; 'Arbutus\_MoFo' <Arbutus\_MoFo@mofo.com>; Parrado, Alvaro <alvaro.parrado@kirkland.com>; Elenberg, Falicia <felenberg@wc.com>; Komis, Jihad <JKomis@wc.com>; Genevant Team <GenevantTeam@wc.com>; Berl, David <DBerl@wc.com>; Mahaffy, Shaun <SMahaffy@wc.com>; Harber, Adam <AHarber@wc.com>; Fletcher, Thomas <TFletcher@wc.com>; Ryen, Jessica <JRyen@wc.com>; 'NTan@mofo.com' <NTan@mofo.com>; Bolte, Erik <ebolte@wc.com>; \*jshaw@shawkeller.com <jshaw@shawkeller.com>; 'kkeller@shawkeller.com' <kkeller@shawkeller.com>; 'nhoeschen@shawkeller.com' <nhoeschen@shawkeller.com>; 'EWiener@mofo.com' <EWiener@mofo.com>; 'began@mnat.com' <began@mnat.com>; 'tmurray@morrisnichols.com' <tmurray@morrisnichols.com>; 'jblumenfeld@morrisnichols.com' <jblumenfeld@morrisnichols.com>; Hurst, James F. <james.hurst@kirkland.com>; Carson, Patricia A. <patricia.carson@kirkland.com>; Wacker, Jeanna <jeanna.wacker@kirkland.com>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information) - HIGHLY CONFIDENTIAL OCEO

Tony,

In follow-up to our November 10 email relating to the production of samples from 400+ lots of expired drug product, we are continuing to work through the burdensome exercise of setting up the logistics to make said production, which we now expect to be in a position to do in January. We will provide an update with additional information as soon as we are able.

Regards,

Alina

**Alina Afinogenova**

**KIRKLAND & ELLIS LLP**

200 Clarendon Street, Boston, MA 02116

**T** +1 617 385 7526 **M** +1 917 324 5094

**F** +1 212 446 4900

[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)



**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Wednesday, November 29, 2023 6:16 PM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Haunschild, Philip <[phaunschild@wc.com](mailto:phaunschild@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>; Elenberg, Falcia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [jshaw@shawkeller.com](mailto:jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information) - HIGHLY CONFIDENTIAL OCEO

Mark,

Could you please let us know if Moderna has an update regarding our questions on sample shipping and storage? If there additional arrangements that need to be made, we'd like to start putting them in place. Thanks.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [vcard](mailto:vcard)**

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**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Monday, November 20, 2023 6:06 PM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Haunschild, Philip <[phaunschild@wc.com](mailto:phaunschild@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>; Elenberg, Falcia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [jshaw@shawkeller.com](mailto:jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>;

'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information) - HIGHLY CONFIDENTIAL OCEO

Mark and Alina,

Further to Moderna's November 10 email and the meet-and-confer on November 17, Plaintiffs understand that Moderna's production of the ~480 batches/lots referenced below does not resolve the parties' dispute as to the remaining batches, but we appreciate Moderna's efforts to narrow the scope of the parties' dispute. We understand that the ~480 batches Moderna is agreeing to produce are being transferred by a third-party to another location. We also understand that Moderna is not withholding samples as to post-complaint batches. We understand that Moderna is looking into whether there are post-complaint batches that are due to imminently expire and that the parties' should have ample time before expiry to address samples from Moderna's ongoing booster production.

Plaintiffs are willing to consider covering the cost for Moderna to ship the samples and/or for a courier. As discussed, please let us know an estimate of the shipping costs. Additionally, we'd appreciate information regarding storage conditions and the capacity needed to store the samples. Assuming that the conditions are as before (*e.g.*, minus 80 degree Celsius), Plaintiffs currently have 90% capacity left in a 19.4 cubic feet (549 L) freezer with interior dimensions of 51.2 in x 23.1 in x 28.3 (H x W x D, 130.1 cm x 58.8 cm x 97.37 cm) and will acquire additional space if needed. The shipping address would be:

Triclinic Labs, Inc.

Attn: Sample Submission

2660 Schuyler Ave. Ste. A.

Lafayette, IN 47905

Plaintiffs understand that Moderna considers batches that were not manufactured or imported into the U.S. to be batches "not accused of infringement." As outlined in previous correspondence, Plaintiffs disagree that such batches are not accused. *See, e.g., E.g.*, D.I. 1 ¶¶ 50–54, 70, 89, 108, 130, 154. Plaintiffs understand that Moderna is investigating the scope of documents it is willing to produce concerning these batches, including its agreements with the relevant third-parties for sales of such batches (besides the U.S. Government, and whether located in the United States or abroad, and whether to a public or private entity), its communications with such third-parties concerning sales or offers to sell batches of the Accused Product, documents evidencing the location and timing of any negotiations or meetings regarding such sales, and Moderna's marketing and strategic plans regarding such sales. Such documents are responsive to at least Plaintiffs' RFPs 51, 53, 60, 64, 69, 74, 75, 81, and 83. Please confirm the scope of documents that Moderna will agree to produce by December 1, 2023.

Best,

Tony

**Anthony Sheh | Associate | Williams & Connolly LLP |** (202) 434-5436 | [vcard](mailto:vcard)

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**From:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>  
**Sent:** Thursday, November 16, 2023 11:07 AM  
**To:** Haunschild, Philip <[phaunschild@wc.com](mailto:phaunschild@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>  
**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>; Elenberg, Falcia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>  
**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information) - HIGHLY CONFIDENTIAL OCEO

Hi Philip,

We are not available before 3pm ET today, but can be available tomorrow before 12pm ET or between 1 and 3pm ET.

Thank you,  
Alina

**Alina Afinogenova**

**KIRKLAND & ELLIS LLP**

200 Clarendon Street, Boston, MA 02116

**T** +1 617 385 7526 **M** +1 917 324 5094

**F** +1 212 446 4900

[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)

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**From:** Haunschild, Philip <[phaunschild@wc.com](mailto:phaunschild@wc.com)>  
**Sent:** Wednesday, November 15, 2023 11:20 AM  
**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>  
**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin

<[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>; Elenberg, Falcia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information) - HIGHLY CONFIDENTIAL OCEO

Hi Mark,

Thank you for your email. Please let us know when Moderna is available to meet-and-confer tomorrow before 3:00 PM (ET) regarding Moderna's proposal as to the samples that Moderna has agreed to produce. We have a number of questions that we would like to address on the meet-and-confer, including at least the following:

- Does your email mean to draw a distinction between the "lots" that Moderna is agreeing to produce and the "batches" that the parties have previously been discussing? We understand these to be interchangeable terms, but please let us know if that is wrong.
- How did Moderna select the approximately 480 lots that it has agreed to produce samples from?
- Is Moderna refusing to produce samples from any unexpired lots?
- Will Moderna be producing samples from lots manufactured after February 28, 2022, the date of the filing of the complaint?
- For part numbers with unexpired lots, will Moderna be producing both expired and unexpired lots from the same part number?
- What is Moderna's position as to representativeness and the ability to argue non-infringement of lots that Moderna is not agreeing to produce samples from?
- Has Moderna determined whether there are additional part numbers for Drug Product or mRNA-LNP beyond those that we have identified in our October 31, 2023 email?

Further, regarding the batches that Moderna will be providing samples from, we have made clear in multiple meet-and-confers in March, April, and November, and in separate correspondence, *e.g.*, March 3, 2023 Letter from A. Sheh; May 11, 2023 Letter from L. Cash, that Moderna's refusal to

provide discovery on the basis that certain batches were simply manufactured abroad is improper. Moderna cannot shield batches from discovery based on Moderna's own self-serving analysis of whether such batches infringe. *See, e.g., California Inst. of Tech. v. Broadcom Ltd.*, 25 F.4th 976, 992 (Fed. Cir. 2022); *Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1308 (Fed. Cir. 2015). Plaintiffs are entitled to take relevant discovery regarding all batches that have been accused of infringement. Please be prepared to discuss this on our meet-and-confer. Please also be prepared to explain how Moderna is determining what batches "can be accused of infringement."

Thank you,

**Philip N. Haunschild**

**Associate | Williams and Connolly LLP**

680 Maine Avenue SW, Washington, DC 20024

202-434-5979 [phaunschild@wc.com](mailto:phaunschild@wc.com) | [www.wc.com](http://www.wc.com)

---

**From:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>

**Sent:** Friday, November 10, 2023 3:00 PM

**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>; Elenberg, Falcia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information) - HIGHLY CONFIDENTIAL OCEO

**CONTAINS INFORMATION MODERNA HAS DESIGNATED HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY**

Counsel,

Regarding Plaintiffs' questions from the meet-and-confer on the number of vials per lot Moderna is able to produce from regulatory retains, we confirm that Moderna maintains its agreement to produce 3 vials per lot. This is proportional to the needs of the case in light of the extensive data Moderna is agreeing to produce about each lot, in the absence of any explanation from Plaintiffs as to why more than 3 vials is needed, and due to Moderna's need to retain samples for regulatory and

compliance purposes, as laid out in detail in our October 20, 2023 letter.

With regard to the number of accused lots that Moderna will produce samples from, in the spirit of compromise and in an effort to narrow the dispute, Moderna is preparing to produce samples of 3 vials of expired drug product from approximately 480 lots. We will provide the lot numbers shortly, but can confirm they correspond to the part numbers below. Moderna will produce (if not already produced) specifications for these part numbers and CoAs for each lot later today or Monday (we are still waiting for the final production volume). Moderna will continue to making rolling productions of additional CoAs and specifications for accused batches as we review them, but we wanted to prioritize these 480 lots first.



Moderna will make this production in the spirit of compromise and does so without waiving any objections to Plaintiffs' RFPs for samples from the remaining accused batches (both the number of samples and quantity of lots). Moderna also makes this production without any representations that the expired drug product is representative of its characteristics at release. Moderna will agree to this production if Plaintiffs agree to pay for the shipping costs or arrange a courier to collect the vials in a single shipment – please confirm Plaintiffs' position by COB November 15, including confirmation of a shipping address if Plaintiffs request that Moderna ship the samples.

We are confirming the exact timing of the production but we understand it can be made in the next two weeks.

Regarding your questions on the batches at issue in this case, we're surprised by Plaintiffs' recent change in position, attempting to dramatically expand the scope of discovery at this late stage. Moderna has been consistent and clear in its position that it would not provide discovery on batches not accused of infringement:

- Moderna's February 2, 2023 Objections to 1<sup>st</sup> RFPs (including general objection: "Moderna objects to Plaintiffs' requests to the extent they seek information, documents, and/or things relating to batches and doses of the Accused Products not accused of infringement, including batches of doses of the Accused Products not made, used, offered for sale, or sold within the United States or imported into the United States, which are not accused of infringement. Moderna will not produce irrelevant information, documents, and/or things concerning such

batches and doses.”)

- Moderna’s April 17, 2023 Objections to Rog. 11 (“Moderna objects to this Interrogatory to the extent it seeks information related to the identity of manufactured lots and/or batches that were not made, used, offered for sale, or sold within the United States or imported into the United States.”)
- McLennan Sept. 19, 2023 Letter (“Moderna offered to produce samples of drug product that were made with each part number of mRNA-LNP that was made, sold, or imported into the U.S.”)
- McLennan July 21, 2023 Email (“Moderna confirms it has produced information in MRNA-GEN-00456085 and MRNA-GEN-00456086 showing batches of Moderna’s COVID-19 Vaccine manufactured *in the U.S.*”)

Our objections to Interrogatory No. 11, and all correspondence concerning it since then have been crystal clear that Moderna is properly limiting discovery concerning batches to those that can be accused of infringement. Although you take statements from our August 1, 2023 letter out of context, in reality we repeated the same objection in that letter. McLennan August 1, 2023 Letter (“Moderna did not agree that Moderna is broadly required to “produce information regarding that foreign activity.” . . . If you have support indicating that batches made outside the U.S. and never imported into the U.S. can constitute infringement of a U.S. patent, we remain willing to consider it.”). Despite Moderna consistently placing Plaintiffs on notice of its position, Plaintiffs delayed raising this purported issue for months. Unfortunately this appears to be yet another attempt to delay resolution of the sample dispute and **exponentially** increase the burden of Moderna’s discovery.

Regards,  
Mark

**Mark C. McLennan**

**KIRKLAND & ELLIS LLP**

601 Lexington Avenue, New York, NY 10022

T +1 212 909 3451

[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)

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**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Tuesday, November 7, 2023 11:42 AM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Elenberg, Falicia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com'



<[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Alina,

Thanks for your email and for confirming that Moderna will be producing CoAs and specifications, as well as responding to Plaintiffs' inquiry regarding the number of vials Moderna is willing to produce per batch, this week. The part numbers below were intended to assist Moderna, necessitated by Moderna's incomplete responses to Plaintiffs' Interrogatories Nos. 6 and 11, and based on Plaintiffs' efforts to analyze information that has been readily available in the first instance to Moderna, not Plaintiffs. We appreciate that Moderna will be producing CoAs and specifications this week, but both of these have been the subject of months-long requests. Plaintiffs have been prejudiced and continue to be prejudiced by Moderna's delays.

With respect your points below regarding batches purportedly "not accused of infringement," Plaintiffs' Complaint alleges that Moderna infringes the patent-in-suit by *inter alia* "manufacturing, offering to sell, selling, or using within the United States, the Accused Product." *E.g.*, D.I. 1 ¶¶ 70, 89, 108, 130, 154. The Complaint further addresses "doses made in the United" but "administered abroad," contracts Moderna has entered worldwide, and "emergency authorizations" for Moderna's COVID-19 vaccine "from more than 70 countries, including Canada, Israel, the United Kingdom, Switzerland, Singapore, Qatar, Taiwan, and the Philippines, as well as from the European Union." D.I. 1 ¶¶ 50–54. With respect to "foreign" batches, Moderna's August 1, 2023 letter (at 7) acknowledges that Moderna's response to Plaintiffs' Interrogatory No. 11 "may provide all of the information Plaintiffs want and/or need," but Moderna has not supplemented its response to Interrogatory No. 11. In any event, Moderna cannot unilaterally shield from discovery batches it contends were assertedly "not made, sold, used, or imported into the U.S." *See, e.g., Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1308 (Fed. Cir. 2015) ("Places of seeming relevance [to a sale] include a place of inking the legal commitment to buy and sell and a place of delivery . . . and perhaps also a place where other 'substantial activities of the sales transactions' occurred."). Plaintiffs are entitled to discovery into these issues and to test Moderna's as-of-yet unsupported contentions. Moderna's email suggests, contrary to its August 1, 2023 letter, that Moderna's response to Interrogatory No. 11 in fact will *not* include information on batches Moderna contends to be "not accused of infringement" on the basis of such batches being "ex-US" or "OUS," which is improper.

Please therefore confirm (1) that the batches Moderna has "identified to date" extends to *all* of the batches Moderna has manufactured and/or sold, regardless of whether that activity occurred in the United States or purportedly not, (2) that Moderna's responses to Plaintiffs' Interrogatory Nos. 6 and 11 will not exclude batches simply because Moderna deems them to be batches "not accused of



infringement,” and (3) that Moderna’s listing or identification of part numbers for the purpose of sample production will include *all* batches. To the extent that Moderna has been excluding “ex-US” or “OUS” batches from discovery, please inform us of Moderna’s basis for doing so. Please provide Moderna’s confirmation by this Friday, November 10, 2023, so that Plaintiffs can promptly seek relief from the Court if necessary.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [vcard](#)**

---

**From:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>

**Sent:** Friday, November 3, 2023 5:35 PM

**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Elenberg, Falcia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

**CONTAINS INFORMATION MODERNA HAS DESIGNATED HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY**

Tony,

As we will explain in more detail when we respond to your letter on Plaintiffs’ 2nd set of RFPs, in the spirit of compromise, next week we expect to produce Moderna’s CoAs for accused batches of [REDACTED] identified to-date. We trust this (in addition to the drug product genealogy spreadsheet) will resolve many, if not all, of your questions below. We expect to produce additional specifications next week too, and are still investigating whether a complete listing of part numbers exists.

We note that from your email below, which lists many part numbers not referenced in earlier correspondence, Plaintiffs appear to now be seeking information concerning batches that were not made, sold, used, or imported into the U.S. and thus not accused of infringement. Moderna has

been clear in its objections to the RFPs, and in correspondence concerning samples since then, that Moderna is not producing samples from batches that are not accused of infringement. We maintain that such batches bear no relevance to this litigation, and thus collection of samples and information from those batches is unduly burdensome and not proportionate to the needs of the case.

We hope to get back to you next week on whether Moderna agrees to produce more than 3 vials per batch.

Have a nice weekend,  
Alina

**Alina Afinogenova**

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**KIRKLAND & ELLIS LLP**

200 Clarendon Street, Boston, MA 02116

**T** +1 617 385 7526 **M** +1 917 324 5094

**F** +1 212 446 4900

[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Tuesday, October 31, 2023 2:53 PM

**To:** Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Elenberg, Falicia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

CONTAINS INFORMATION MODERNA HAS DESIGNATED HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY

Mark,

Plaintiffs understood from our meet-and-confer on October 23, 2023, that Moderna would be getting back to us last week regarding whether it would be willing to produce more than three vials from a batch. Could you please let us know by COB tomorrow the results of Moderna's investigation?

Likewise, Plaintiffs have been working to narrow the parties' dispute regarding samples with respect to the number of vials. For Moderna's convenience, we have been able to identify the following drug product part numbers based on information Moderna has produced to date: [REDACTED]

[REDACTED] Could you please confirm whether there are any other drug product part numbers that are at issue, including for ex-US batches? We have excluded "unlabeled" drug product part numbers from this set, but if those are relevant, please let us know. For the part numbers that are *not* in bold, we have been unable to identify a specification sheet in MRNA-GEN-VOL013 to ascertain the lipid content per vial. Could you please confirm that Moderna will produce these specification sheets this week?

[REDACTED] We understand from Moderna's August 24, 2023 letter that it has been working to collect and produce specifications for each part number relevant to batches of the Accused Product.

We are happy to discuss any of the foregoing by phone if helpful. Thanks.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [vcard](#)**

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**From:** Parrado, Alvaro <[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)>

**Sent:** Friday, October 20, 2023 6:28 PM

**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Elenberg, Falcia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com'

<[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>;  
'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F.  
<[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna  
<[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Counsel,

Please see the attached case correspondence.

Thank you,

**Alvaro R. Parrado**

Senior Paralegal | Intellectual Property

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**KIRKLAND & ELLIS LLP**

601 Lexington Avenue, New York, NY 10022

**T** +1 212 909 3407 **M** +1 212-960-8542

**F** +1 212 446 4900

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[alvaro.parrado@kirkland.com](mailto:alvaro.parrado@kirkland.com)

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Friday, October 20, 2023 5:58 PM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; McLennan, Mark C.  
<[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Elenberg, Falcia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad  
<[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo'  
<[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>;  
Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica  
<[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>;  
<[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)> <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com'  
<[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>;  
'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin  
<[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com'  
<[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>;  
'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F.  
<[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna  
<[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Thanks Alina. We can use the following dial-in:

**Call in (audio only)**

+1 872-242-8083, 149140221# United States, Chicago

Phone Conference ID: 149 140 221#

[Find a local number](#)

**Anthony Sheh | Associate | Williams & Connolly LLP |** (202) 434-5436 | [vcard](#)

---

**From:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>

**Sent:** Friday, October 20, 2023 1:11 PM

**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Elenberg, Falicia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Tony,

We are available at 2:30pm ET on Monday.

Regards,  
Alina

**Alina Afinogenova**

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**KIRKLAND & ELLIS LLP**

200 Clarendon Street, Boston, MA 02116

**T** +1 617 385 7526 **M** +1 917 324 5094

**F** +1 212 446 4900

---

[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)

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**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Friday, October 20, 2023 11:39 AM

**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Elenberg, Falicia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com'

<NTan@mofo.com>; Bolte, Erik <ebolte@wc.com>; \*jshaw@shawkeller.com  
<jshaw@shawkeller.com>; 'kkeller@shawkeller.com' <kkeller@shawkeller.com>;  
'nhoeschen@shawkeller.com' <nhoesch@shawkeller.com>; 'EWiener@mofo.com'  
<EWiener@mofo.com>

**Cc:** #KEModernaSpikeVaxService <KEModernaSpikeVaxService@kirkland.com>; Li, Yan-Xin  
<yanxin.li@kirkland.com>; Horstman, N. Kaye <kaye.horstman@kirkland.com>; 'began@mnat.com'  
<began@mnat.com>; 'tmurray@morrisnichols.com' <tmurray@morrisnichols.com>;  
'jblumenfeld@morrisnichols.com' <jblumenfeld@morrisnichols.com>; Hurst, James F.  
<james.hurst@kirkland.com>; Carson, Patricia A. <patricia.carson@kirkland.com>; Wacker, Jeanna  
<jeanna.wacker@kirkland.com>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Mark,

Since it appears that Moderna believes that the parties may still have a dispute, please let us know when you are available to meet and confer on Monday with Delaware counsel present. Plaintiffs are available after 12 p.m. ET. We look forward to receiving Moderna's response regarding samples later today. Thanks.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [vcard](#)**

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**From:** McLennan, Mark C. <mark.mclennan@kirkland.com>

**Sent:** Friday, October 20, 2023 10:52 AM

**To:** Sheh, Anthony <ASheh@wc.com>; Elenberg, Falcia <felenberg@wc.com>; Afinogenova, Alina  
<alina.afinogenova@kirkland.com>; Komis, Jihad <JKomis@wc.com>; Genevant Team  
<GenevantTeam@wc.com>; 'Arbutus\_MoFo' <Arbutus\_MoFo@mofo.com>; Berl, David  
<DBerl@wc.com>; Mahaffy, Shaun <SMahaffy@wc.com>; Harber, Adam <AHarber@wc.com>;  
Fletcher, Thomas <TFletcher@wc.com>; Ryen, Jessica <JRyen@wc.com>; 'NTan@mofo.com'  
<NTan@mofo.com>; Bolte, Erik <ebolte@wc.com>; \*jshaw@shawkeller.com  
<jshaw@shawkeller.com>; 'kkeller@shawkeller.com' <kkeller@shawkeller.com>;  
'nhoeschen@shawkeller.com' <nhoesch@shawkeller.com>; 'EWiener@mofo.com'  
<EWiener@mofo.com>

**Cc:** #KEModernaSpikeVaxService <KEModernaSpikeVaxService@kirkland.com>; Li, Yan-Xin  
<yanxin.li@kirkland.com>; Horstman, N. Kaye <kaye.horstman@kirkland.com>; 'began@mnat.com'  
<began@mnat.com>; 'tmurray@morrisnichols.com' <tmurray@morrisnichols.com>;  
'jblumenfeld@morrisnichols.com' <jblumenfeld@morrisnichols.com>; Hurst, James F.  
<james.hurst@kirkland.com>; Carson, Patricia A. <patricia.carson@kirkland.com>; Wacker, Jeanna  
<jeanna.wacker@kirkland.com>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Tony,

Thanks for your email. We're still investigating a couple of outstanding issues concerning the samples in an effort to try to narrow the issues in dispute, and hope to respond later today. We'll be available to meet and confer after that whenever Plaintiffs are ready.

We disagree that Moderna has delayed this process; instead Moderna has worked expeditiously to investigate ways to reach a compromise on Plaintiffs' unreasonable demands.

Thanks,  
Mark

**Mark C. McLennan**

**KIRKLAND & ELLIS LLP**

601 Lexington Avenue, New York, NY 10022

T +1 212 909 3451

[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Friday, October 20, 2023 8:35 AM

**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Elenberg, Falicia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Mark,

Thanks for your note. Plaintiffs understood that we would be hearing back from Moderna yesterday regarding sample production, which is a months (if not years) long dispute that Plaintiffs have taken significant efforts to resolve with Moderna to no avail. Plaintiffs have been prejudiced by Moderna's delays in this process.

Please let us know your availability to meet and confer today so that we can promptly raise this dispute with the Court.



We will await Moderna's response to our October 6, 2023 letter regarding Moderna's R&D documents, but note that Plaintiffs raised the issues therein in our meet-and-confer on September 15, 2023, and we have been waiting over a month for a response.

Thanks.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [vcard](#)**

---

**From:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>

**Sent:** Wednesday, October 18, 2023 10:09 AM

**To:** Elenberg, Falicia <[felenberg@wc.com](mailto:felenberg@wc.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Falicia,

Thank you for your email. We are hoping to get back to you today or tomorrow on the samples issue.

We are also reviewing your October 6 letter on "R&D-related documents" which addresses the same RFPs that Plaintiffs separately wrote to us about in two other letters on October 9. We are preparing a response to those three letters and will get back to you as soon as possible. We note we've been waiting for a response to our September 7 letter on Moderna's 1<sup>st</sup> set of RFPs for six weeks now.

Thanks,  
Mark

**Mark C. McLennan**



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**KIRKLAND & ELLIS LLP**

601 Lexington Avenue, New York, NY 10022

T +1 212 909 3451

[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)

---

**From:** Elenberg, Falicia <[felenberg@wc.com](mailto:felenberg@wc.com)>

**Sent:** Wednesday, October 18, 2023 9:59 AM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Counsel,

You have not responded to our October 6th letters regarding sample production and R&D-related documents, nor have we heard back from you regarding your availability to meet-and-confer on the matter. Plaintiffs are highly prejudiced by Defendants' refusal to produce and resolve these crucial categories of material. Please let us know your availability to meet-and-confer today (Oct. 18th) or tomorrow (Oct. 19th). If we do not hear from you regarding a time to meet-and-confer by close of business today, Plaintiffs' will consider the parties to be at an impasse.

Best,  
Falicia

**Falicia Elenberg**

**Law Clerk | Williams & Connolly LLP**

680 Maine Avenue, S.W., Washington, DC 20024

202-434-5989 | [felenberg@wc.com](mailto:felenberg@wc.com) | [www.wc.com](http://www.wc.com)

---

**From:** Elenberg, Falicia

**Sent:** Monday, October 16, 2023 8:57 AM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Counsel,

We have not received response to our October 6, 2023 letters concerning sample production and Moderna's production of documents relating to its research and development of the Accused Product. So that Plaintiffs can promptly resolve these disputes, could you please let us know your availability tomorrow or Wednesday to meet and confer? We are available tomorrow (Tuesday) from 11 a.m. – 12 p.m. and 2p.m. – 3 p.m. ET or Wednesday before 2 p.m. ET. Thanks.

Best,  
Falicia

**Falicia Elenberg**

**Law Clerk | Williams & Connolly LLP**

680 Maine Avenue, S.W., Washington, DC 20024

202-434-5989 | [felenberg@wc.com](mailto:felenberg@wc.com) | [www.wc.com](http://www.wc.com)

---

**From:** Elenberg, Falicia <[felenberg@wc.com](mailto:felenberg@wc.com)>

**Sent:** Friday, October 6, 2023 6:04 PM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Hello all,

Please see the attached correspondence.

**Falicia Elenberg**

**Law Clerk | Williams & Connolly LLP**

680 Maine Avenue, S.W., Washington, DC 20024

202-434-5989 | [felenberg@wc.com](mailto:felenberg@wc.com) | [www.wc.com](http://www.wc.com)

---

**From:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>

**Sent:** Tuesday, October 3, 2023 8:17 PM

**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; NTan@mofo.com; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Hi Tony,

Based on the meet-and-confer last week, we understand the parties are each going to reconsider their positions and respond.

In the meantime, please confirm that Plaintiffs will reimburse Moderna for the doses and the associated shipping and handling costs. For example, Plaintiffs' current request for the equivalent of 100 mg of lipids per batch, and samples from 10% of batches, could exceed 10,000 doses, which is clearly a significant expense and burden on Moderna.

Thank you,  
Alina

**Alina Afinogenova**

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**KIRKLAND & ELLIS LLP**

200 Clarendon Street, Boston, MA 02116

**T** +1 617 385 7526 **M** +1 917 324 5094

**F** +1 212 446 4900

[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Wednesday, September 27, 2023 6:32 PM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; NTan@mofo.com; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Thanks Alina, that works for us. We can use the following dial-in:

**Call in (audio only)**

[+1 872-242-8083](tel:+18722428083), [631822421](tel:+1631822421)# United States, Chicago

Phone Conference ID: 631 822 421#

[Find a local number](#)

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [vcard](#)**

---

**From:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>

**Sent:** Wednesday, September 27, 2023 11:08 AM

**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; NTan@mofo.com; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Tony,

We can be available at 2pm ET on Thursday.

Regards,  
Alina

**Alina Afinogenova**

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**KIRKLAND & ELLIS LLP**

200 Clarendon Street, Boston, MA 02116

**T** +1 617 385 7526 **M** +1 917 324 5094

**F** +1 212 446 4900

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[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Tuesday, September 26, 2023 9:28 PM

**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Hi Mark,

Unfortunately 4 p.m. tomorrow doesn't work for us. Would sometime on Thursday from 1–4 p.m. ET work? Thanks.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP |** (202) 434-5436 | [vcard](mailto:vcard)

---

**From:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>

**Sent:** Monday, September 25, 2023 4:31 PM

**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>;

Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Tony,

We're available on Wednesday at 4pm ET.

Thanks,  
Mark

**Mark C. McLennan**

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**KIRKLAND & ELLIS LLP**

601 Lexington Avenue, New York, NY 10022

T +1 212 909 3451

---

[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Friday, September 22, 2023 10:01 PM

**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

With apologies to all who celebrate—I forgot that Monday is Yom Kippur. As such, please let us know if Tuesday or Wednesday would work. Thanks.

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [ycard](mailto:ycard)**

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>  
**Sent:** Friday, September 22, 2023 9:45 PM  
**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)  
**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>  
**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Mark,

Could you please let us know your availability to meet and confer regarding your September 19 letter this Monday or Tuesday? Thanks.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [vcard](mailto:vcard)**

---

**From:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>  
**Sent:** Tuesday, September 19, 2023 5:05 PM  
**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)  
**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>  
**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Tony,



Please see the attached letter. We're available to meet and confer.

Thanks,  
Mark

**Mark C. McLennan**

---

**KIRKLAND & ELLIS LLP**

601 Lexington Avenue, New York, NY 10022

T +1 212 909 3451

[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Monday, September 18, 2023 8:21 PM

**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [jshaw@shawkeller.com](mailto:jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Mark,

Could you please provide Moderna's response to Plaintiffs' September 6 letter regarding samples? As we noted in the letter, this dispute has been pending for more than 8 months, and Plaintiffs intend to raise this dispute with the Court shortly if the parties cannot reach agreement. Thanks.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP | (202) 434-5436 | [vcard](mailto:vcard)**

---

**From:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>

**Sent:** Friday, September 8, 2023 5:14 PM

**To:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica



<[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com)  
<[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com);  
[EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Li, Yan-Xin  
<[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com);  
[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F.  
<[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna  
<[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Tony,

We're in receipt of your letter from Wednesday night. We note that you took two weeks to respond to our August 24 letter and demanded a response within two days. We are looking into questions raised in your letter, including numerous new inquiries, and will respond next week.

Best,  
Mark

**Mark C. McLennan**

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**KIRKLAND & ELLIS LLP**

601 Lexington Avenue, New York, NY 10022

T +1 212 909 3451

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[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)

---

**From:** Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>

**Sent:** Wednesday, September 6, 2023 10:31 PM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>;  
Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl,  
David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>;  
Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte,  
Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>;  
[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; McLennan, Mark C.  
<[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye  
<[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com);  
[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A.  
<[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Counsel,

Please see the attached correspondence. Thank you.

Best,  
Tony

**Anthony Sheh | Associate | Williams & Connolly LLP |** (202) 434-5436 | [vcard](#)

---

**From:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>

**Sent:** Thursday, August 24, 2023 12:23 PM

**To:** Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; NTan@mofo.com <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; \*jshaw@shawkeller.com <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Cc:** #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Counsel,

Please see the attached correspondence.

Regards,  
Alina

**Alina Afinogenova**

---

**KIRKLAND & ELLIS LLP**

200 Clarendon Street, Boston, MA 02116

T +1 617 385 7526 M +1 917 324 5094

F +1 212 446 4900

[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)

---

**From:** Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>

**Sent:** Wednesday, August 16, 2023 6:10 PM

**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Cc:** Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Berl, David

<[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

Counsel,

Please see the attached correspondence. Thanks.

Regards,  
Jihad

**Jihad J. Komis**

**Associate | Williams & Connolly LLP**

680 Maine Avenue SW, Washington, D.C., 20024

(P) 202-434-5166 | (F) 202-434-5029

[JKomis@wc.com](mailto:JKomis@wc.com) | [www.wc.com](http://www.wc.com)

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**From:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>

**Sent:** Friday, July 21, 2023 2:18 PM

**To:** Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Cc:** Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoesch@shawkeller.com](mailto:nhoesch@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel (Batch Information)

**CONFIDENTIAL**

Jihad,

Moderna confirms it has produced information in MRNA-GEN-00456085 and MRNA-GEN-00456086 showing batches of Moderna's COVID-19 Vaccine manufactured in the U.S. As we've noted to Plaintiffs many times, the information is burdensome to investigate, and we produced this listing now based on our current investigation to date at Plaintiffs' request. We are still months from close of fact discovery and we will update it as our investigation continues, if needed.

As you know, the parties repeatedly agreed to continue discussing further sample availability once we were able to produce batch history information. Now that Plaintiffs have this batch listing showing more than one thousand batches, please let us know if Plaintiffs are maintaining their request for "50 vials . . . from each" batch. As you can imagine, investigating the availability of this unreasonable and unjustified number of vials across more than one thousand batches is extremely burdensome. We have repeatedly asked Plaintiffs for months to explain why they need 50 vials from each lot, and have not received a response. Moderna maintains its objections to Plaintiffs' RFPs and Interrogatories in the meantime and reserves all rights.

We look forward to hearing from Plaintiffs about the availability of samples in response to Moderna's RFP No. 125 too.

Regards,  
Mark

**Mark C. McLennan**

**KIRKLAND & ELLIS LLP**

601 Lexington Avenue, New York, NY 10022

T +1 212 909 3451

[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)

---

**From:** Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>

**Sent:** Thursday, July 20, 2023 6:04 PM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Cc:** Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com); [jshaw@shawkeller.com](mailto:jshaw@shawkeller.com); [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel

Counsel,

We are in receipt of Moderna's production of July 19, 2023, including the natives produced at MRNA-GEN-00456085 and MRNA-GEN-00456086, which purport to identify batches of Moderna's finished drug product. Could you please confirm whether these documents identify the batches of the Accused Product that Moderna has manufactured to date? Relatedly, we have not heard from

Moderna regarding Plaintiffs' email below dated July 13, 2023, regarding the availability of samples from batches of the Accused Product. Could you please confirm that Moderna will provide this information this week?

Regards,  
Jihad

**Jihad J. Komis**

**Associate | Williams & Connolly LLP**

680 Maine Avenue SW, Washington, D.C., 20024

(P) 202-434-5166 | (F) 202-434-5029

[JKomis@wc.com](mailto:JKomis@wc.com) | [www.wc.com](http://www.wc.com)

---

**From:** Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>

**Sent:** Thursday, July 13, 2023 4:57 PM

**To:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Cc:** Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com); [jshaw@shawkeller.com](mailto:jshaw@shawkeller.com); [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel

Counsel,

Thank you for your response. Plaintiffs understand that Moderna has agreed to provide a listing of batch/lot numbers of Moderna's finished drug product by next week. However, Moderna's July 12, 2023 letter does not address Plaintiffs' other longstanding inquiry regarding the availability of samples from those batches. Please confirm that Moderna will provide this information next week, as well.

For avoidance of doubt, Plaintiffs have not agreed to modify the scope of information sought by Interrogatory Nos. 6 and 11, which we understand that Moderna intends to answer substantively later this month. Plaintiffs expect that Moderna will answer the full scope of those interrogatories, and not just provide the "simple listing" referred to in your letter. We disagree with Moderna's assertion that the scope of Interrogatories No. 6 and 11, which seek highly relevant information regarding infringement and damages, imposes any burden with respect to information that Moderna agreed to provide *four months ago*, i.e., a "simple listing" of batches and the availability of samples from those batches. In any event, please confirm that Moderna intends to answer the full scope of Interrogatories Nos. 6 and 11, and is not unilaterally limiting the scope of Plaintiffs' interrogatories based on a misunderstanding of the

information Plaintiffs need regarding samples.

Finally, we disagree with the implications in your letter that Moderna's ongoing failure to provide routine discovery information is in any way justified by its request for thousands of prototype formulations sought by RFP No. 125, including those that are not sold or manufactured by Plaintiffs. Moderna's unjustified delay continues to prejudice Plaintiffs' ability to discuss the production of samples of the Accused Product which are at the heart of this case. Plaintiffs reserve all rights.

Regards,  
Jihad

**Jihad J. Komis**

**Associate | Williams & Connolly LLP**

680 Maine Avenue SW, Washington, D.C., 20024

(P) 202-434-5166 | (F) 202-434-5029

[JKomis@wc.com](mailto:JKomis@wc.com) | [www.wc.com](http://www.wc.com)

---

**From:** Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>

**Sent:** Wednesday, July 12, 2023 8:50 AM

**To:** Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>; McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Cc:** Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com) <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel

Counsel,

Please see the attached correspondence.

Best regards,  
Alina

**Alina Afinogenova**

---

**KIRKLAND & ELLIS LLP**

200 Clarendon Street, Boston, MA 02116

**T** +1 617 385 7526 **M** +1 917 324 5094

**F** +1 212 446 4900

---

[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)

---

**From:** Komis, Jihad <[JKomis@wc.com](mailto:JKomis@wc.com)>

**Sent:** Tuesday, July 11, 2023 5:17 PM

**To:** McLennan, Mark C. <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; Afinogenova, Alina <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; Li, Yan-Xin <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; Horstman, N. Kaye <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; [began@mnat.com](mailto:began@mnat.com); [tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com); [jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com); Hurst, James F. <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; Carson, Patricia A. <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; Wacker, Jeanna <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Cc:** Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; Arbutus\_MoFo <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; #KEModernaSpikevaxService <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; [NTan@mofo.com](mailto:NTan@mofo.com); Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; [\\*jshaw@shawkeller.com](mailto:*jshaw@shawkeller.com); [jshaw@shawkeller.com](mailto:jshaw@shawkeller.com); [kkeller@shawkeller.com](mailto:kkeller@shawkeller.com); [nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com); [EWiener@mofo.com](mailto:EWiener@mofo.com)

**Subject:** RE: Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel

Counsel,

We have not received any response to our June 29, 2023 correspondence once again requesting that Moderna identify batches of the Accused Product and the availability of samples. As set forth in our correspondence, despite Moderna agreeing months ago to provide this information so that the parties could continue discussing sample production, as well as multiple letters and meet-and-confers on this issue, Moderna continues to withhold this information and has failed to even provide a date certain when it intends to supply it. To date, Moderna has not articulated any reasonable basis for not promptly providing this basic accounting information, and Moderna's unjustified delay continues to prejudice Plaintiffs' ability to litigate this case.

Given Plaintiffs' multiple letters and the parties' multiple meet-and-confers on this issue, Plaintiffs understand that the parties are at an impasse. Plaintiffs thus intend to move the Court this Friday, July 14, 2023, for an order compelling Moderna to identify all batches of the Accused Product and the availability of samples unless Moderna immediately provides this information.

Thank you.

Regards,  
Jihad

**Jihad J. Komis**

**Associate | Williams & Connolly LLP**

680 Maine Avenue SW, Washington, D.C., 20024

(P) 202-434-5166 | (F) 202-434-5029

[JKomis@wc.com](mailto:JKomis@wc.com) | [www.wc.com](http://www.wc.com)

---

**From:** Komis, Jihad

**Sent:** Thursday, June 29, 2023 5:17 PM

**To:** 'mark.mclennan@kirkland.com' <[mark.mclennan@kirkland.com](mailto:mark.mclennan@kirkland.com)>; 'alina.afinogenova@kirkland.com' <[alina.afinogenova@kirkland.com](mailto:alina.afinogenova@kirkland.com)>; 'yanxin.li@kirkland.com' <[yanxin.li@kirkland.com](mailto:yanxin.li@kirkland.com)>; 'kaye.horstman@kirkland.com' <[kaye.horstman@kirkland.com](mailto:kaye.horstman@kirkland.com)>; 'began@mnat.com' <[began@mnat.com](mailto:began@mnat.com)>; 'tmurray@morrisnichols.com' <[tmurray@morrisnichols.com](mailto:tmurray@morrisnichols.com)>; 'jblumenfeld@morrisnichols.com' <[jblumenfeld@morrisnichols.com](mailto:jblumenfeld@morrisnichols.com)>; 'james.hurst@kirkland.com' <[james.hurst@kirkland.com](mailto:james.hurst@kirkland.com)>; 'patricia.carson@kirkland.com' <[patricia.carson@kirkland.com](mailto:patricia.carson@kirkland.com)>; 'jeanna.wacker@kirkland.com' <[jeanna.wacker@kirkland.com](mailto:jeanna.wacker@kirkland.com)>

**Cc:** Genevant Team <[GenevantTeam@wc.com](mailto:GenevantTeam@wc.com)>; 'Arbutus\_MoFo' <[Arbutus\\_MoFo@mofo.com](mailto:Arbutus_MoFo@mofo.com)>; 'KEModernaSpikevaxService@kirkland.com' <[KEModernaSpikevaxService@kirkland.com](mailto:KEModernaSpikevaxService@kirkland.com)>; Berl, David <[DBerl@wc.com](mailto:DBerl@wc.com)>; Mahaffy, Shaun <[SMahaffy@wc.com](mailto:SMahaffy@wc.com)>; Harber, Adam <[AHarber@wc.com](mailto:AHarber@wc.com)>; Sheh, Anthony <[ASheh@wc.com](mailto:ASheh@wc.com)>; Fletcher, Thomas <[TFletcher@wc.com](mailto:TFletcher@wc.com)>; Ryen, Jessica <[JRyen@wc.com](mailto:JRyen@wc.com)>; 'NTan@mofo.com' <[NTan@mofo.com](mailto:NTan@mofo.com)>; Bolte, Erik <[ebolte@wc.com](mailto:ebolte@wc.com)>; 'jshaw@shawkeller.com' <[jshaw@shawkeller.com](mailto:jshaw@shawkeller.com)>; 'kkeller@shawkeller.com' <[kkeller@shawkeller.com](mailto:kkeller@shawkeller.com)>; 'nhoeschen@shawkeller.com' <[nhoeschen@shawkeller.com](mailto:nhoeschen@shawkeller.com)>; 'EWiener@mofo.com' <[EWiener@mofo.com](mailto:EWiener@mofo.com)>

**Subject:** Arbutus v. Moderna, 1-22-cv-00252 - Letter to Counsel

Counsel,

Please see the attached correspondence. Thank you.

Regards,

Jihad

**Jihad J. Komis**

**Associate | Williams & Connolly LLP**

680 Maine Avenue SW, Washington, D.C., 20024

(P) 202-434-5166 | (F) 202-434-5029

[JKomis@wc.com](mailto:JKomis@wc.com) | [www.wc.com](http://www.wc.com)

---

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# **Exhibit 5**

LAW OFFICES  
**WILLIAMS & CONNOLLY**<sub>LLP</sub>\*

ANTHONY H. SHEH  
(202) 434-5436  
asheh@wc.com

680 MAINE AVENUE SW  
WASHINGTON, DC 20024  
(202) 434-5000  
WWW.WC.COM

EDWARD BENNETT WILLIAMS (1920-1988)  
PAUL R. CONNOLLY (1922-1978)

October 6, 2023

**HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY**

**Via Email**

Mark C. McLennan  
KIRKLAND & ELLIS LLP  
601 Lexington Avenue  
New York, NY 10022  
(212) 909-3451  
mark.mclennan@kirkland.com

Re: *Arbutus Biopharma Corporation and Genevant Sciences GmbH v. Moderna, Inc. and ModernaTX, Inc.*, Case 1:22-cv-00252-MSG (D. Del.)

Dear Mark:

I write in response to Moderna’s September 19, 2023 letter regarding Moderna’s sample production and to memorialize the discussion from our September 28, 2023 meet-and-confer.

**I. Production of Finished Drug Product**

Thank you for clarifying Moderna’s proposed scope of sample production set forth in your August 24, 2023 and September 19, 2023 letters on our meet-and-confer. As discussed, Plaintiffs understand that Moderna proposes to produce 3 vials of finished drug product, from a single batch, per part number of mRNA-1273 LNP, which—based on the 13 part numbers Plaintiffs have been able to identify to date from Moderna’s limited document production—amounts to 39 vials total from 13 batches.

Needless to say, Plaintiffs disagree that it is reasonable for Moderna to limit its sample production to 39 vials from 13 batches where millions of vials have been manufactured and sold across approximately a thousand batches. Moderna has no basis for disputing the relevance of samples with respect to *each* batch of the Accused Product—which unlike the urine test cups at issue in *Rembrandt Diagnostics, LP v. Innovacon, Inc.*, 2017 WL 4391707 (S.D. Cal. Oct. 3, 2017), cited in Moderna’s September 19, 2023 letter, vary in a manner that Moderna is maintaining the right to argue is relevant to infringement. The purpose of Plaintiffs’ request is not to “burden and harass” Moderna as your September 19, 2023 letter contends without basis. The quantity of

WILLIAMS & CONNOLLY<sup>LLP</sup>

October 6, 2023

Page 2 of 4

samples Plaintiffs have requested is proportionate in light of the nature of Moderna's product, as well as Moderna's decision to infringe Plaintiffs' patents willfully and on a massive scale. As to Moderna's assertion that Plaintiffs have been "unresponsive" to Moderna's questions about Plaintiffs' requested quantity of samples, we have made clear that the requested quantities are needed for testing and in light of Moderna's position that it may dispute infringement on a batch-by-batch basis. Regardless, those questions do not justify Moderna's months-long delay in providing a mere "simple listing" of the batches it has manufactured to date. Moderna's presumption that Plaintiffs require only 3 micrograms to run a lipid content assay based on an analytical method produced by Genevant for a different product is misplaced, *see* GENV-00038004 at \*38006, as is Moderna's contention that Plaintiffs intend to run 240,000 tests. Neither of Moderna's contentions is correct. Plaintiffs seek samples from the relevant population of infringing batches and sufficient quantity from each batch—100 milligrams—which is a fraction of the LNP content generated at Moderna's commercial manufacturing scales. *See, e.g.*, MRNA-GEN-00040016 at \*40024 ("[REDACTED]") (emphasis added).

Nevertheless, in light of Moderna's assertions regarding the burden of producing samples from each batch, Plaintiffs have indicated their willingness to compromise and reduce their request even further to what amounts to a tiny fraction of the total number of batches and material that Moderna has manufactured to date. *See* Letter from A. Sheh to M. McLennan (Sept. 6, 2023) at 3–4. Plaintiffs also acknowledge Moderna's assertion that it is burdensome even to identify the number of samples available from each batch, notwithstanding Moderna's representation for the first time on our September 29, 2023 meet-and-confer that it initially reserves a set standard amount of Accused Product following the manufacture of each batch of the drug product for regulatory purposes. As requested on our meet-and-confer, please identify the standard amounts Moderna has used for its regulatory retain.

As discussed on our meet-and-confer, Plaintiffs propose the following compromise on the scope of sample production, which represents an even further reduction in what Plaintiffs proposed in our September 6, 2023 letter.

- 1) Plaintiffs will select 50 finished drug batches distributed across the mRNA-1273 LNP part numbers identified by Moderna. To the extent that Moderna wishes to select additional batches, it may do so.<sup>1</sup>
- 2) To the extent that Moderna is not able to provide a sufficient number of vials to provide 100 mg of LNP for a batch selected by Plaintiffs, Plaintiffs may substitute another batch for which 100 mg of LNP can be provided.

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<sup>1</sup> Plaintiffs reiterate that this proposal is based on their understanding of the available mRNA-1273 LNP part numbers to date. Moderna has not identified the relevant mRNA-1273 LNP part numbers and Plaintiffs reserve the right to adjust the number of batches based on additional and/or new information that is brought to Plaintiffs' attention.

WILLIAMS & CONNOLLY<sup>LLP</sup>

October 6, 2023

Page 3 of 4

- 3) Moderna will stipulate that the batches in a given mRNA-1273 LNP part number are representative of all batches within that part number and will not contend that batches not produced by Moderna do not infringe should Plaintiffs prove that batch representative of a part number infringes.

We understand that Moderna is considering Plaintiffs proposal, which we provided on our September 28, 2023 meet-and-confer. Please provide Moderna's response by October 12, 2023, so that Plaintiffs can promptly seek relief from the Court if necessary. Plaintiffs have already been prejudiced by Moderna's months-long delay.

## II. RFP Nos. 110 and 111

In RFPs 110 and 111, Plaintiffs requested documents related to the analytical testing, and samples of, the Accused Product intermediate formed [REDACTED]. Moderna has repeatedly and improperly asserted that such samples are irrelevant. Moderna mischaracterizes such samples as being distinct from the Accused Product and argues that Plaintiffs have failed to assert infringement claims over such samples. That is wrong. Such samples plainly relate to Plaintiffs' claims that Moderna has infringed through manufacturing the Accused Product incorporating Arbutus's patent LNP technology, and by selling, importing, and inducing others to make and use a product that embodies a component of a patented manufacture, combination or composition. *E.g.*, Complaint, D.I. 1 ¶¶ 70–73; *see also*, *e.g.*, Plaintiffs Initial Infringement Contentions, Paragraph 4(c) Chart of U.S. Patent No. 8,058,069 at 1 (“[REDACTED]”).

During our meet-and-confer, Moderna asserted that it would not be feasible to produce the [REDACTED] form of the Accused Product. [REDACTED] Moderna refused to identify the individuals at Moderna who provided this confirmation on the basis of work product. In light of these assertions, please confirm that Moderna will produce samples of the [REDACTED]. We raised this request on our September 28, 2023 call, and we understand that Moderna is investigating our request.

On the assumption that Moderna desires to produce less than all batches of [REDACTED] used to manufacture the Accused Product and will agree to representativeness on the basis of part numbers, Plaintiffs are willing to discuss a compromise analogous to the proposal above regarding the finished drug product. Please confirm by October 12, 2023 that Moderna is willing to produce samples of [REDACTED].

WILLIAMS & CONNOLLY<sup>LLP</sup>

October 6, 2023

Page 4 of 4

Finally, on our call and in Moderna's email dated October 3, 2023, Moderna raised the notion of cost-shifting regarding sample production. What Plaintiffs are requesting is basic discovery that is merited in light of positions that Moderna has taken in this case, and therefore cost-shifting is not appropriate. To the extent that you have contrary authority, please provide it so that Plaintiffs can consider Moderna's position. Please also describe and quantify the costs that Moderna contends should be subject to cost-shifting. Please note, however, that such discussion should not provide any basis to further delay Moderna from providing this basic discovery.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony Sheh", written in a cursive style.

Anthony H. Sheh

cc: Counsel of Record

# **Exhibit 6**



## KIRKLAND & ELLIS LLP

AND AFFILIATED PARTNERSHIPS

Mark C. McLennan  
To Call Writer Directly:  
+1 212 909 3451  
mark.mclennan@kirkland.com

601 Lexington Avenue  
New York, NY 10022  
United States

+1 212 446 4800

www.kirkland.com

Facsimile:  
+1 212 446 4900

October 20, 2023

**By Email**

**HIGHLY CONFIDENTIAL –  
OUTSIDE COUNSEL EYES ONLY**

Anthony Sheh  
Williams & Connolly LLP  
680 Maine Ave SW  
Washington, DC 20024  
asheh@wc.com

Shaelyn K. Dawson  
Morrison & Foerster LLP  
425 Market Street  
San Francisco, CA, 94105  
shaelyndawson@mofo.com

Re: *Arbutus Biopharma Corporation et al. v. Moderna, Inc. et al.*, C.A. No. 22-252-MSG (D. Del.) – **Samples**

Counsel:

We write regarding the parties' September 28, 2023 meet-and-confer and Plaintiffs' October 6, 2023 letter.

We understand that Plaintiffs' current proposal is as follows: Plaintiffs seek samples of drug product vials containing the equivalent of 100 mg lipid content from each of 50 finished drug batches that Plaintiffs' will select across the mRNA-1273 LNP part numbers identified by Moderna.

Thank you for agreeing to meet and confer again on Monday, October 23.

**1. Drug Product Samples**

Plaintiffs' persist in ignoring important, undisputed facts in their continued request for an extreme and unreasonable volume of samples.

First, this is not a situation where testing and related documentation does not already exist. Plaintiffs continue to ignore that Moderna has already produced data concerning the lipid content of its product generally and each batch individually, and has committed to further producing additional testing data kept in the ordinary course regarding the lipid content of each batch. The fact that Plaintiffs appear to just not like the results of such testing does not automatically make the production of large amounts of samples necessary or proportionate with respect to resolution of the issues in this case.

## KIRKLAND &amp; ELLIS LLP

Anthony Sheh; Shaelyn K. Dawson

October 20, 2023

Page 3

It also appears that Plaintiffs are taking the position that they cannot determine lipid content of the drug product as it exists in the ordinary course (i.e., as sold) by Moderna,<sup>2</sup> and instead are seeking these samples with the intent to somehow combine samples to amass 100 mg of lipid. Plaintiffs have been entirely unwilling to compromise—maintaining their request for vials equivalent 100 mg of lipid per batch since serving the RFP in December 2022. Further, despite months of meeting and conferring, Plaintiffs informed Moderna for the first time during the September 28, 2023 meet-and-confer that they refused to reduce the amount of samples they were seeking.

With respect to your questions regarding Moderna's regulatory retained samples of drug product, Moderna's standard operating procedure is compliant with FDA's regulation under 21 CFR 211-170, which requires a reserved sample that is representative of each lot in each shipment be retained, and that the quantity of the reserved sample be two times the quantity sufficient to perform all the required tests (except for sterility and pyrogens). For any drug product batch where Moderna only has regulatory retained samples, which is likely to be the case for many older drug product batches,

particularly for any non-expired batch, as Moderna needs those samples for regulatory and/or compliance purposes.

For the purposes of this litigation, Moderna expects to be able to produce up to three vials of drug product across drug product lots that have expired. As described above and in our September 19, 2023 letter, Moderna would produce those 3 vials from one batch of each of the different part numbers. Consistent with Moderna's earlier sample production, Moderna would retain 3 corresponding samples for purposes of this litigation. With respect to expired drug product, Moderna would produce samples with the understanding that the expired materials may not exhibit the same lot characteristics demonstrated at the time of initial release. In the absence of any justification from Plaintiffs as to why 100 mg of lipid content per batch is needed, Moderna's proposal is reasonable and proportional to the needs of the case.

Finally, with regard to recently manufactured batches, as we previously explained, Moderna is currently working to rapidly distribute Moderna's updated booster product for this fall season. Plaintiffs' requests for large amounts of samples (equivalent to 100 mg of lipid per batch) are unnecessary for the reasons mentioned above, as well as burdensome to the extent Plaintiffs seek a significant diversion of product from the market and doses for patient use.

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<sup>2</sup> For example, a [REDACTED] mL drug product vial containing [REDACTED] mg/mL of lipid, would total [REDACTED] mg lipid content. *See* MRNA\_GEN\_00456568 (Part Number 70153). Another exemplary drug product part number contains [REDACTED] mg lipid content per vial. *See* MRNA\_GEN\_00456733 (Part Number 70065).

# **Exhibit 7**

# **Filed Under Seal**

# **Exhibit 8**

# **Filed Under Seal**

# Exhibit 9

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION )  
and GENEVANT SCIENCES GmbH, )

Plaintiffs, )

v. )

C.A. No. 22-252 (MSG)

MODERNA, INC. and MODERNATX, INC., )

Defendants. )

---

MODERNA, INC. and MODERNATX, INC., )

Counterclaim-Plaintiffs, )

v. )

ARBUTUS BIOPHARMA CORPORATION )  
and GENEVANT SCIENCES GmbH, )

Counterclaim-Defendants. )

**DEFENDANTS' OBJECTIONS AND RESPONSES TO PLAINTIFFS'  
FIRST SET OF REQUESTS FOR PRODUCTION (NOS. 1–98)**

Pursuant to Fed. R. Civ. P. 34, Defendants Moderna, Inc. and ModernaTX Inc. (collectively, “Moderna” or “Defendants”) respond to Plaintiffs Arbutus Biopharma Corporation (“Arbutus”) and Genevant Sciences GmbH’s (“Genevant,” and collectively, “Plaintiffs”) First Set of Requests for Production (“Requests” and each individually, a “Request”).

**GENERAL OBJECTIONS**

The following general responses and objections apply to each individual response to Plaintiffs’ Requests, as if fully set forth therein. The failure to repeat any of the following General Objections in the specific responses below shall not be deemed a waiver of such objection or limitation.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 2:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “[a]ll documents related to the preparation of” BLA No. 125752, which presumes that all such documents are relevant. Moderna will not search for or produce irrelevant documents, including documents relating to aspects of the Accused Products that are not relevant to the Asserted Claims. Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it lacks reasonable temporal restrictions. Moderna objects to this Request to the extent it seeks proprietary, confidential, or trade secret information of Moderna or of others to whom Moderna is under an obligation of confidentiality (by agreement or by law). Moderna also objects to this Request as seeking the production of documents protected from discovery by the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Moderna will not produce such documents.

Subject to and without waiving any of its general or specific objections, Moderna will produce BLA No. 125752, excluding subsections containing patient Personal Identifiable Information.

**REQUEST FOR PRODUCTION NO. 3:**

A copy of any other U.S. or foreign regulatory submission relating to approval or emergency authorization of the Accused Product, including all correspondence, amendments, and supplements relating thereto.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 3:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “any other U.S. or foreign regulatory submission relating to approval or emergency authorization of the Accused Product,” which presumes that all such documents are relevant. Moderna will not search for or produce irrelevant documents, including documents relating to aspects of the Accused Products that are not relevant to the Asserted Claims. Moderna will not search for or produce regulatory submissions relating to doses that were not made, used, offered for sale, or sold within the United States or imported into the United States, which are not accused of infringement. Moderna objects to this Request to the extent it seeks proprietary, confidential, or trade secret information of Moderna or of others to whom Moderna is under an obligation of confidentiality (by agreement or by law).

Subject to and without waiving any of its general or specific objections, Moderna will produce a copy of BLA No. 125752, IND 19745, and EUA No. 27073, as well as supplements and amendments thereto, excluding subsections containing patient Personal Identifiable Information.

**REQUEST FOR PRODUCTION NO. 4:**

All documents related to the research and development of the Accused Product.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 4:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “[a]ll documents related to the research and development of the Accused Product,” which presumes that all such documents are relevant. Moderna will not search for or produce irrelevant documents, including documents relating to



**REQUEST FOR PRODUCTION NO. 97:**

50 vials of the Accused Product from each lot referenced in Biologics License Application 125752 or that has otherwise been manufactured by or on behalf of Moderna, and the material safety data sheet and any handling and storage instructions and histories for each sample.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 97:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “50 vials of the Accused Product from *each* lot referenced in Biologics License Application 125752 or that has otherwise been manufactured by or on behalf of Moderna, and the material safety data sheet and *any* handling and storage instructions and histories for *each* sample” (emphasis added), which presumes all such samples and information are relevant. Moderna will not produce samples and information that are irrelevant and/or not proportional to the needs of this case. Moderna objects to the request for 50 vials of each lot as overly broad and unduly burdensome and not proportionate to the needs of the case. Moderna objects to this Request to the extent it seeks documents not within Moderna’s custody, possession or control. Moderna objects to the term “histories” as vague and undefined.

Subject to and without waiving any of its general or specific objections, Moderna is willing to meet and confer regarding this Request.

**REQUEST FOR PRODUCTION NO. 98:**

A 10 g sample (divided into five 2 g aliquots) of each ingredient in the Accused Product, and the material safety data sheet and any handling and storage instructions and histories for each sample.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 98:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional

to the needs of this case, including because it seeks “a 10 g sample . . . of each ingredient in the Accused Product,” which presumes all such ingredients are relevant to the Asserted Claims. Moderna will not produce samples and information that are irrelevant and/or not proportional to the needs of this case. Moderna objects to the Request for 10 g samples as overly broad and unduly burdensome and not proportionate to the needs of the case. Moderna objects to this Request to the extent it seeks material equally available to Plaintiffs.

Subject to and without waiving any of its general or specific objections, Moderna is willing to meet and confer regarding this Request.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Brian P. Egan*

OF COUNSEL:

James F. Hurst  
KIRKLAND & ELLIS LLP  
300 North LaSalle  
Chicago, IL 60654  
(312) 862-2000

Patricia A. Carson, Ph.D.  
Jeanna M. Wacker, P.C.  
Mark C. McLennan  
KIRKLAND & ELLIS LLP  
601 Lexington Avenue  
New York, NY 10022  
(212) 446-4800

February 2, 2023

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Jack B. Blumenfeld (#1014)  
Brian P. Egan (#6227)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@morrisnichols.com  
began@morrisnichols.com

*Attorneys for Defendants*

**CERTIFICATE OF SERVICE**

I hereby certify that on February 2, 2023, copies of the foregoing were caused to be served upon the following in the manner indicated:

John W. Shaw, Esquire  
Karen E. Keller, Esquire  
Nathan R. Hoeschen, Esquire  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
*Attorneys for Plaintiffs Arbutus Biopharma  
Corporation and Genevant Sciences GmbH*

*VIA ELECTRONIC MAIL*

Daralyn J. Durie, Esquire  
Eric C. Wiener, Esquire  
MORRISON & FOERSTER LLP  
425 Market Street  
San Francisco, CA 94105-2482  
*Attorneys for Plaintiff Arbutus Biopharma  
Corporation*

*VIA ELECTRONIC MAIL*

Kira A. Davis, Esquire  
MORRISON & FOERSTER LLP  
707 Wilshire Boulevard  
Los Angeles, CA 90017-3543  
*Attorneys for Plaintiff Arbutus Biopharma  
Corporation*

*VIA ELECTRONIC MAIL*

David I. Berl, Esquire  
Adam D. Harber, Esquire  
Thomas S. Fletcher, Esquire  
Jessica Palmer Ryen, Esquire  
Lydia B. Cash, Esquire  
Shaun P. Mahaffy, Esquire  
WILLIAMS & CONNOLLY LLP  
680 Maine Avenue S.W.  
Washington, DC 20024  
*Attorneys for Plaintiff Genevant Sciences  
GmbH*

*VIA ELECTRONIC MAIL*

*/s/ Brian P. Egan*

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Brian P. Egan (#6227)

# **Exhibit 10**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION	)	
and GENEVANT SCIENCES GmbH,	)	
	)	
Plaintiffs,	)	C.A. No. 22-252 (MSG)
	)	
v.	)	<b>HIGHLY CONFIDENTIAL –</b>
	)	<b>OUTSIDE COUNSEL’S EYES ONLY</b>
MODERNA, INC. and MODERNATX, INC.	)	
	)	<b>JURY TRIAL DEMANDED</b>
Defendants.	)	
MODERNA, INC. and MODERNATX, INC.,	)	
	)	
Counterclaim-Plaintiffs,	)	
	)	
v.	)	
	)	
ARBUTUS BIOPHARMA CORPORATION	)	
and GENEVANT SCIENCES GmbH,	)	
	)	
Counterclaim-Defendants.	)	

**DEFENDANTS’ RESPONSES AND OBJECTIONS TO PLAINTIFFS’ SECOND SET OF REQUESTS FOR PRODUCTION TO DEFENDANTS (NOS. 99–127)**

Pursuant to Federal Rules of Civil Procedure 26 and 34, Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, “Moderna” or “Defendants”) provide their responses and objections to Plaintiffs Arbutus Biopharma Corporation (“Arbutus”) and Genevant Sciences GmbH (“Genevant”)’s requests for production.

**GENERAL OBJECTIONS**

Moderna incorporates by reference its General Objections provided in Moderna’s Responses and Objections to Plaintiffs’ First Set of Requests for Production to Defendants (Nos. 1–98) served February 2, 2023.

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proportional to the needs of this case, specifically because it lacks reasonable temporal restrictions. Moderna objects to this Request as vague and ambiguous, at least with respect to the phrase “any finished drug product,” which is not defined. Moderna objects to this Request to the extent it seeks documents that are protected by confidentiality obligations to third parties that prohibit or restrict their disclosure by Moderna (by agreement or by law) and will not produce such documents. Moderna objects to this Request as duplicative of at least RFP No. 18. Moderna objects to this Request as duplicative of at least RFP Nos. 1–3, in response to which Moderna has already agreed to produce a copy of BLA No. 125752, IND 19745, and EUA No. 27073, as well as supplements and amendments thereto, excluding subsections containing patient Personal Identifiable Information.

Subject to and without waiving any of its general or specific objections, Moderna is willing to meet and confer regarding this Request.

**REQUEST FOR PRODUCTION NO. 108:**

All documents and communications, including raw data and lab notebooks, related to any analytical testing by or on behalf of Moderna concerning lipid molar ratios of the Accused Product, including any testing of [REDACTED], mRNA-1273 LNP, and finished drug product, and any testing performed under any version of SOP-0502, SOP-0878, and SOP-1001.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 108:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “[a]ll documents and communications, including raw data and lab notebooks, related to any analytical testing by or on behalf of Moderna concerning lipid molar ratios of the Accused Product” as described, potentially encompassing an enormous number of documents, which presumes that all such documents, communications, and testing are relevant. Moderna will not produce irrelevant and/or non-responsive documents,

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including documents relating to aspects of the Accused Products that are not relevant to the Asserted Claims and documents relating to testing of intermediates [REDACTED], which are not relevant to the Asserted Claims. Moderna will not produce documents related solely to non-accused components such as [REDACTED]. Moderna will not search for documents relating to batches of the Accused Products (and materials used in those batches) that were not made, used, offered for sale, or sold within the United States or imported into the United States, which are not accused of infringement. Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it lacks reasonable temporal restrictions. Moderna objects to this Request as vague and ambiguous, at least with respect to the phrase “finished drug product,” which is not defined. Moderna objects to this Request as seeking the production of documents protected from discovery by the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Moderna will not produce such documents. Moderna objects to this Request to the extent it seeks documents that are protected by confidentiality obligations to third parties that prohibit or restrict their disclosure by Moderna (by agreement or by law) and will not produce such documents. Moderna objects to this Request as duplicative of at least RFP Nos. 14, 15, 18, 21, 25, 26, 30, 31, and 34. Moderna also objects to this Request as duplicative of at least RFP Nos. 1–3, in response to which Moderna has already agreed to produce a copy of BLA No. 125752, IND 19745, and EUA No. 27073, as well as supplements and amendments thereto, excluding subsections containing patient Personal Identifiable Information.

Subject to and without waiving any of its general or specific objections, Moderna will produce non-privileged documents relating to the characterization of Moderna’s COVID-19

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Vaccine, and mRNA-1273 LNP used to manufacture Moderna’s COVID-19 Vaccine, with respect to the lipid molar ratios of Moderna’s COVID-19 Vaccine identified after a reasonable and proportionate search.

**REQUEST FOR PRODUCTION NO. 109:**

All versions of any analytical method used by or on behalf of Moderna for testing related to lipid molar ratios of the Accused Product, including any testing of [REDACTED], mRNA-1273 LNP, and finished drug product, and including all versions of SOP-0502, SOP-0878, and SOP-1001.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 109:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “[a]ll versions of any analytical method used by or on behalf of Moderna for testing related to lipid molar ratios of the Accused Product” as described, potentially encompassing an enormous number of documents, which presumes that all such documents are relevant. Moderna will not produce irrelevant and/or non-responsive documents, including documents relating to aspects of the Accused Products that are not relevant to the Asserted Claims and documents relating to testing of intermediates [REDACTED] [REDACTED], which are not relevant to the Asserted Claims. Moderna will not produce documents related solely to non-accused components such as [REDACTED]. Moderna will not search for documents relating to batches of the Accused Products (and materials used in those batches) that were not made, used, offered for sale, or sold within the United States or imported into the United States, which are not accused of infringement. Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it lacks reasonable temporal restrictions. Moderna objects to this Request as



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seeking the production of documents protected from discovery by the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Moderna will not produce such documents. Moderna objects to this Request to the extent it seeks documents that are protected by confidentiality obligations to third parties that prohibit or restrict their disclosure by Moderna (by agreement or by law) and will not produce such documents. Moderna objects to this Request as duplicative of at least RFP Nos. 27, 32, and 33. Moderna also objects to this Request as duplicative of at least RFP Nos. 1–3, in response to which Moderna has already agreed to produce a copy of BLA No. 125752, IND 19745, and EUA No. 27073, as well as supplements and amendments thereto, excluding subsections containing patient Personal Identifiable Information.

Subject to and without waiving any of its general or specific objections, Moderna will produce non-privileged documents relating to the analytical methods used for measuring the lipid ratios of the LNPs in Moderna’s COVID-19 Vaccine, and the mRNA-1273 LNP used to manufacture Moderna’s COVID-19 Vaccine, identified after a reasonable and proportionate search.

**REQUEST FOR PRODUCTION NO. 110:**

All documents and communications related to any analytical testing of any intermediate formed during the manufacturing process for mRNA-1273 LNP [REDACTED]. See, e.g., MRNA-GEN-00081770 at \*81774.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 110:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “[a]ll documents and communications related to any analytical testing of any intermediate formed during the manufacturing process for mRNA-1273 LNP [REDACTED],” potentially encompassing an enormous

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number of documents, which presumes that all such documents are relevant. Moderna will not produce irrelevant and/or non-responsive documents, including documents relating to testing of intermediates [REDACTED], which are not relevant to the Asserted Claims. Moderna will not search for documents relating to batches of the Accused Products (and materials used in those batches) that were not made, used, offered for sale, or sold within the United States or imported into the United States, which are not accused of infringement. Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it lacks reasonable temporal restrictions. Moderna objects to this Request as vague and ambiguous, at least with respect to the phrase “intermediate,” which is not defined. Moderna objects to this Request as seeking the production of documents protected from discovery by the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Moderna will not produce such documents. Moderna objects to this Request to the extent it seeks documents that are protected by confidentiality obligations to third parties that prohibit or restrict their disclosure by Moderna (by agreement or by law) and will not produce such documents. Moderna also objects to this Request as duplicative of at least RFP Nos. 31 and 34. Moderna also objects to this Request as duplicative of at least RFP Nos. 1–3, in response to which Moderna has already agreed to produce a copy of BLA No. 125752, IND 19745, and EUA No. 27073, as well as supplements and amendments thereto, excluding subsections containing patient Personal Identifiable Information.

Subject to and without waiving any of its general or specific objections, Moderna is willing to meet and confer regarding this request.

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**REQUEST FOR PRODUCTION NO. 111:**

A 10 g sample (divided into five 2 g aliquots) from each manufacturing run for each batch or lot of the Accused Product manufactured by or for Moderna of the intermediate formed during manufacturing process for mRNA-1273 LNP [REDACTED]. See, e.g., MRNA-GEN-00081770 at \*81774.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 111:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “sample from *each* manufacturing run for *each* batch or lot of the Accused Product . . . of the intermediate formed during manufacturing process for mRNA-1273 LNP” (emphasis added), which presumes all such samples are relevant. Moderna will not produce materials irrelevant to any claim of defense asserted in this litigation, including samples of intermediates [REDACTED], which are not relevant to the Asserted Claims. Moderna will not search for documents and/or materials relating to batches of the Accused Products (and materials used in those batches) that were not made, used, offered for sale, or sold within the United States or imported into the United States, which are not accused of infringement. Moderna objects to the request for samples “from *each* manufacturing run for *each* batch or lot of the Accused Product” as overly broad and unduly burdensome and not proportionate to the needs of the case. Moderna objects to this Request as vague and ambiguous, at least with respect to the phrase “intermediate,” which is not defined. Moderna objects to this Request to the extent it seeks documents and/or materials not within Moderna’s custody, possession or control.

Subject to and without waiving any of its general or specific objections, Moderna is willing to meet and confer regarding this request.

**HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY**

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Brian P. Egan*

OF COUNSEL:

James F. Hurst  
KIRKLAND & ELLIS LLP  
300 North LaSalle  
Chicago, IL 60654  
(312) 862-2000

Patricia A. Carson, Ph.D.  
Jeanna M. Wacker, P.C.  
Mark C. McLennan  
Nancy Kaye Horstman  
KIRKLAND & ELLIS LLP  
601 Lexington Avenue  
New York, NY 10022  
(212) 446-4800

Yan-Xin Li  
KIRKLAND & ELLIS LLP  
555 California Street, 27th Floor  
San Francisco, CA 94104  
(415) 439-1400

Alina Afinogenova  
KIRKLAND & ELLIS LLP  
200 Clarendon Street  
Boston, MA 02116  
(617) 385-7500

June 26, 2023

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Jack B. Blumenfeld (#1014)  
Brian P. Egan (#6227)  
Travis J. Murray (#6882)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@morrisnichols.com  
began@morrisnichols.com  
tmurray@morrisnichols.com

*Attorneys for Defendants*

**CERTIFICATE OF SERVICE**

I hereby certify that on June 26, 2023, copies of the foregoing were caused to be served upon the following in the manner indicated:

John W. Shaw, Esquire  
Karen E. Keller, Esquire  
Nathan R. Hoeschen, Esquire  
Emily S. DiBenedetto, Esquire  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
*Attorneys for Plaintiffs Arbutus Biopharma  
Corporation and Genevant Sciences GmbH*

*VIA ELECTRONIC MAIL*

Daralyn J. Durie, Esquire  
Adam R. Brausa, Esquire  
Annie A. Lee, Esquire  
Shaelyn K. Dawson, Esquire  
MORRISON & FOERSTER LLP  
425 Market Street  
San Francisco, CA 94105-2482  
*Attorneys for Plaintiff Arbutus Biopharma  
Corporation*

*VIA ELECTRONIC MAIL*

Kira A. Davis, Esquire  
MORRISON & FOERSTER LLP  
707 Wilshire Boulevard  
Los Angeles, CA 90017-3543  
*Attorneys for Plaintiff Arbutus Biopharma  
Corporation*

*VIA ELECTRONIC MAIL*

David N. Tan, Esquire  
MORRISON & FOERSTER LLP  
2100 L Street, NW, Suite 900  
Washington, DC 20037  
*Attorneys for Plaintiff Arbutus Biopharma  
Corporation*

*VIA ELECTRONIC MAIL*

David I. Berl, Esquire  
Adam D. Harber, Esquire  
Thomas S. Fletcher, Esquire  
Jessica Palmer Ryen, Esquire  
Lydia B. Cash, Esquire  
Shaun P. Mahaffy, Esquire  
Anthony H. Sheh, Esquire  
Philip N. Haunschild, Esquire  
Jihad J. Komis, Esquire  
WILLIAMS & CONNOLLY LLP  
680 Maine Avenue S.W.  
Washington, DC 20024  
*Attorneys for Plaintiff Genevant Sciences  
GmbH*

*VIA ELECTRONIC MAIL*

*/s/ Brian P. Egan*

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Brian P. Egan (#6227)

# **Exhibit 11**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION	)	
and GENEVANT SCIENCES GmbH,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. 22-252 (MSG)
	)	
MODERNA, INC. and MODERNATX, INC.	)	<b>HIGHLY CONFIDENTIAL –</b>
	)	<b>OUTSIDE COUNSEL’S EYES ONLY</b>
Defendants.	)	
<hr/> MODERNA, INC. and MODERNATX, INC.,	)	
	)	
Counterclaim-Plaintiffs,	)	
	)	
v.	)	
	)	
ARBUTUS BIOPHARMA CORPORATION	)	
and GENEVANT SCIENCES GmbH,	)	
	)	
Counterclaim-Defendants.	)	

**DEFENDANTS’ RESPONSES AND OBJECTIONS TO PLAINTIFFS’ FOURTH SET OF REQUESTS FOR PRODUCTION TO DEFENDANTS (NOS. 174–175)**

Pursuant to Federal Rules of Civil Procedure 26 and 34, Defendants Moderna, Inc. and ModernaTX, Inc. (collectively, “Moderna” or “Defendants”) provide their responses and objections to Plaintiffs Arbutus Biopharma Corporation (“Arbutus”) and Genevant Sciences GmbH (“Genevant”)’s requests for production (Nos. 174–175).

**GENERAL OBJECTIONS**

Moderna incorporates by reference its General Objections provided in Moderna’s Responses and Objections to Plaintiffs’ First Set of Requests for Production to Defendants (Nos. 1–98) served February 2, 2023.



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Moderna also objects the sheer number of requests, now totaling 175, as unreasonable burdensome, duplicative, and not proportional to the needs of the case, particularly where Plaintiffs expect Moderna to carry out an unreasonable number of searches at this stage in the case.

**DEFINITIONS**

Moderna incorporates by reference the Definitions provided in Moderna’s Responses and Objections to Plaintiffs’ First Set of Requests for Production to Defendants (Nos. 1–98) served February 2, 2023.

**OBJECTIONS TO REQUESTS FOR PRODUCTION**

**REQUEST FOR PRODUCTION NO. 174**

100 mg based on total lipid content of [REDACTED] from each lot or batch referenced in Biologics License Application 125752 or that has otherwise been manufactured by or on behalf of Moderna to manufacture the Accused Product, and the material safety data sheet and any handling and storage instructions and histories for each sample.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 174:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “100 mg based on total lipid content of [REDACTED] [REDACTED] from *each lot or batch* referenced in Biologics License Application 125752 or that has otherwise been manufactured by or on behalf of Moderna to manufacture the Accused Product, and the material safety data sheet and *any* handling and storage instructions and histories for *each* sample” (emphasis added), which presumes all such samples and documents are relevant. Moderna will not produce materials irrelevant to any claim or defense asserted in this litigation, including samples of intermediates [REDACTED], which are not accused of infringement and are not relevant to the Asserted Claims. Moderna will not produce documents or materials relating to batches of the Accused Products (and materials

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used in those batches) that were not made, used, offered for sale, or sold within the United States or imported into the United States, which are not accused of infringement. Moderna objects to the request for [REDACTED] “from each lot or batch” as overbroad, unduly burdensome, and not proportional to the needs of the case. Moderna objects to this Request as vague and ambiguous, at least with respect to the phrase “histories,” which is not defined. Moderna objects to this Request to the extent it seeks documents and materials not within Moderna’s custody, possession, or control. Moderna objects to this Request as overbroad, unduly burdensome, and not proportional to the needs of the case at least because Moderna has produced or will produce certificates of analysis for the [REDACTED] used in accused batches and certificates of analysis for accused batches of Moderna’s COVID-19 Vaccine.

Subject to and without waiving any of its general or specific objections, Moderna will not produce documents and materials responsive to this Request.

**REQUEST FOR PRODUCTION NO. 175**

All documents related to United States Government Accountability Office Report No. 21-319, Operation Warp Speed, Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges, including but not limited to, Moderna’s “questionnaire responses and vaccine development documents” and any documents related to Moderna’s “testimonial evidence.” See <https://www.gao.gov/assets/720/712410.pdf>, at 24.

**RESPONSE TO REQUEST FOR PRODUCTION NO. 175:**

Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, including because it seeks “[a]ll documents related to United States Government Accountability Office Report No. 21-319, Operation Warp Speed, Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges,” which presumes that all such documents are relevant. Moderna will not produce documents concerning this action that do not relate to the issues in dispute and/or the claims and defenses of

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the parties. Moderna objects to this Request as overbroad, unduly burdensome, and calling for information not relevant to any of the claims or defenses in this litigation and/or not proportional to the needs of this case, specifically because it lacks reasonable temporal restrictions. Moderna objects to this Request as seeking the production of documents protected from discovery by the attorney-client privilege, the work-product doctrine, or any other applicable privilege or immunity. Moderna will not produce such documents. Moderna objects to this Request to the extent it seeks proprietary, confidential, or trade secret information of Moderna or of others to whom Moderna is under an obligation of confidentiality (by agreement or by law). Moderna objects to this Request as duplicative of at least RFP No. 6.

Subject to and without waiving any of its general or specific objections, Moderna is willing to meet and confer regarding the scope of this Request.

**HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY**

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Travis J. Murray*

OF COUNSEL:

Patricia A. Carson, Ph.D.  
Jeanna M. Wacker, P.C.  
Mark C. McLennan  
Yan-Xin Li  
Caitlin Dean  
Nancy Kaye Horstman  
Shaoyao Yu  
KIRKLAND & ELLIS LLP  
601 Lexington Avenue  
New York, NY 10022  
(212) 446-4800

Alina Afinogenova  
KIRKLAND & ELLIS LLP  
200 Clarendon Street  
Boston, MA 02116  
(617) 385-7500

---

Jack B. Blumenfeld (#1014)  
Brian P. Egan (#6227)  
Travis J. Murray (#6882)  
1201 North Market Street  
P.O. Box 1347  
Wilmington, DE 19899  
(302) 658-9200  
jblumenfeld@morrisnichols.com  
began@morrisnichols.com  
tmurray@morrisnichols.com

*Attorneys for Defendants*

November 13, 2023

**CERTIFICATE OF SERVICE**

I hereby certify that on November 13, 2023, copies of the foregoing were caused to be served upon the following in the manner indicated:

John W. Shaw, Esquire  
Karen E. Keller, Esquire  
Nathan R. Hoeschen, Esquire  
Emily S. DiBenedetto, Esquire  
SHAW KELLER LLP  
I.M. Pei Building  
1105 North Market Street, 12th Floor  
Wilmington, DE 19801  
*Attorneys for Plaintiffs Arbutus Biopharma  
Corporation and Genevant Sciences GmbH*

*VIA ELECTRONIC MAIL*

Daralyn J. Durie, Esquire  
Adam R. Brausa, Esquire  
Eric C. Wiener, Esquire  
Annie A. Lee, Esquire  
Shaelyn K. Dawson, Esquire  
MORRISON & FOERSTER LLP  
425 Market Street  
San Francisco, CA 94105-2482  
*Attorneys for Plaintiff Arbutus Biopharma  
Corporation*

*VIA ELECTRONIC MAIL*

Kira A. Davis, Esquire  
MORRISON & FOERSTER LLP  
707 Wilshire Boulevard  
Los Angeles, CA 90017-3543  
*Attorneys for Plaintiff Arbutus Biopharma  
Corporation*

*VIA ELECTRONIC MAIL*

David N. Tan, Esquire  
MORRISON & FOERSTER LLP  
2100 L Street, NW, Suite 900  
Washington, DC 20037  
*Attorneys for Plaintiff Arbutus Biopharma  
Corporation*

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David I. Berl, Esquire  
Adam D. Harber, Esquire  
Thomas S. Fletcher, Esquire  
Jessica Palmer Ryen, Esquire  
Shaun P. Mahaffy, Esquire  
Anthony H. Sheh, Esquire  
Philip N. Haunschild, Esquire  
Jihad J. Komis, Esquire  
Matthew W. Lachman, Esquire  
WILLIAMS & CONNOLLY LLP  
680 Maine Avenue S.W.  
Washington, DC 20024  
*Attorneys for Plaintiff Genevant Sciences GmbH*

*VIA ELECTRONIC MAIL*

*/s/ Travis J. Murray*

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Travis J. Murray (#6882)